

COVID-19 Vaccination Plan

GEORGIA

Georgia Department of Public Health 22 APRIL 2022 | V.24

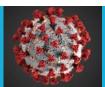
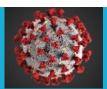
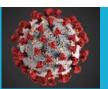


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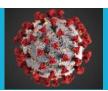
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43. If we need a booster shot, does that mean that the vaccines aren't working?	69
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Yes. Everyone is still considered fully vaccinated two weeks after their second dose in a 2-shot series, such as the Pfizer-BioNTech or Moderna vaccines, or two weeks after a single-dose vaccin such as the J&J/Janssen vaccine.	-
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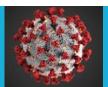
Record of Changes

Date of original version: October 2, 2020

Date Reviewed	Change Number	Date of Change	Description of Change	Name of Author
10/15/2020	1	10/16/2020	Transferred to CDC Template	S. Lovett
11/6/2020	2	11/05/2020	Added verbiage for Critical Populations	N. Dixon
11/6/2020	3	11/05/2020	Added verbiage for Vaccine Storage; Added verbiage for pharmacy enrollment	T. Dabbs
11/6/2020	4	11/06/2020	Added verbiage for LTCF enrollment; Added Appendix F	S. Lovett
11/6/2020	5	11/06/2020	Updates to Section 12 per CDC recommendations	E. Jens A. Tavarez
12/7/2020	6	12/7/2020	Rearranged and formatted Section 2 for better flow	S. Thomas
12/7/2020	7	12/7/2020	Added IMT Organization Chart in Section 2	S. Thomas
12/7/2020	8	12/7/2020	Added a clearer image in Appendix C	S. Thomas
12/7/2020	9	12/7/2020	Revised Phase 1 population section to reflect ACIP Phase 1a recommendation	S. Lovett
12/17/2020	10	12/20/2020	Verified, updated, added internal and external links	S. Thomas
12/17/2020	11	12/20/2020	Updated Phase 1 populations section to reflect ACIP Phase 1b and 1c recommendations	S. Thomas
01/05/2021	12	01/05/2021	Updated Phases populations to include GA's revised phase 1A+ populations	S. Lovett
01/05/2021	13	01/05/2021	Replaced Appendix C with the most current version	N. Nydam
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01/09/2021	15	01/09/2021	Grammar and layout editing	L. Hoffacker
01/10/2021	16	01/10/2021	Updated training and enrollment sections, including links.	L. Hoffacker & T. Dabbs



02/19/2021	17	02/16/2021	Updated to reflect addition of	DPH Vaccine
			Administrative Order, COVID-19	Team
			Program policies; new	
			organizational chart; new	
			notification system; new phase	
			description, and deletion of sunset	
			provisions.	
2/24/2021	18	02/24/2021	Updates to the FAQ Document	S. Lovett
3/4/2021	19	03/04/2021	Addition of eligible populations	G Peacock
10/22/2021	20	10/25/2021	Updated: Index, Executive Summary,	DPH Vaccine
			EUA Updates, VMS, Booster &	Team
			Additional Doses Updates,	
			Appendices (A, C and G), Storage	
			and Handling, Organization Chart,	
			and Phased Approach verbiage.	
12/2/2021	21	12/7/2021	Updated: EUA Updates, ACIP	DPH Vaccine
			Updates, Booster & Additional Team	
			Doses Updates, and Organizational	
			Chart.	
1/11/2022	22	1/11/2022	Updated: EUA Updates, ACIP	DPH Vaccine
			updates, Booster Updates, Provider	Team
			Training Updates, Storage &	
			Handling Updates	
3/9/2022	23	3/9/2022	Updated: EUA Updates, ACIP	DPH Vaccine
			updates, Booster Updates	Team
4/22/2022	24	4/22/2022	Updated: EUA, ACIP updates, DPH Vaccine	
			Booster Updates	Team



Executive Summary

The Georgia Department of Public Health (DPH) understands the development of a successful COVID-19 vaccination program requires a strong partnership between federal, state, and local clinical and non-clinical partners. Through these established partnerships and following guidance from the Centers for Disease Control and Prevention (CDC), DPH is working to assure vaccines are distributed equitably and efficiently across Georgia.

The H1N1 pandemic demonstrated that well planned and executed mass vaccination efforts are an effective method for addressing and slowing the spread of disease resulting from a naturally occurring pandemic. This statewide Mass Vaccination Distribution and Administration Plan will be used as a state protocol for distributing the COVID-19 vaccine to public health districts and other enrolled COVID-19 pandemic vaccine providers, and overseeing their administration of the vaccine to intended receipients.

Phased Approach to COVID-19 Vaccination

Throughout this response, the main goal is to assure vaccine distribution and administration processes are in place to rapidly administer vaccines to Georgia residents. Early assumptions included a possible imbalance between vaccine demand and supply. Provider sites and vaccine shipments were prioritized according to the populations those providers serve and the key populations who have been prioritized for the vaccination effort. Initially, key populations were prioritized using a phased approach based on assessed level of risk for exposure to or complications from the disease.

As of May 2021, all residents of Georgia ages 12 and over are eligible to receive the COVID-19 vaccine. Vaccine supply currently exceeds demand, allowing DPH to focus distribution efforts on identifying vaccine desert to improve vaccine access across Georgia, with a special focus on our underserved populations. DPH continues to expand vaccination efforts to increase uptake for initial vaccine doses, boosters, and additional doses following FDA, CDC, and ACIP recommendations and guidance. Please note: As of November 2021, all residents of Georgia ages 5 and over are eligible to receive the COVID-19 vaccine. Specifically, ages 5 to 17 years are only eligible to receive Pfizer BioNTech mRNA COVID-19 vaccine; while 18 years and older are eligible to choose their preferred COVID-19 vaccine of choice.

Critical Populations

While vaccine supply remained limited, DPH used CDC's ACIP recommendations and the National Academy of Medicine's Framework for Equitable Allocation of COVID-19 Vaccine as guidance, as well as a combination of existing national, state-wide, and local data sources; engagement of community-based organizations, academic institutions, and state agencies; mapping, modeling, and forecasting; and surveillance data to identify critical and priority populations. Currently, efforts have shifted towards assuring access to vaccines for these populations through traditional and non-traditional immunization



settings. DPH utilizes the aforementioned resources and partnerships to identify vaccine deserts across Georgia, and these findings are use to further inform vaccination distribution and provider recruitment efforts.

COVID-19 Vaccination Provider Recruitment and Enrollment

DPH began recruiting COVID-19 vaccine providers in August 2020, by releasing a COVID-19 vaccine provider interest survey. Enrollment has since moved to an online process through the Georgia Registry of Immunization Transactions and Services (GRITS). Active recruitment and enrollment of new providers will continue while the COVID-19 vaccine remains available. Georgia's Immunization Program (GIP) will lead the COVID-19 vaccine enrollment.

COVID-19 Vaccine Storage and Handling

Cold chain storage and handling requirements for each vaccine product will vary from refrigerated (2° to 8° C) to frozen (-25°C to -15°C) to ultra-cold (-90°C to -60°C) temperatures, and ongoing stability testing may impact these requirements. Vaccines must be stored appropriately from the time manufactured until administered to a vaccine recipient. While Providers are not being asked to purchase ultracold storage units, all Providers will be required to follow the CDC, ACIP, and manufacturer's guidance regarding the proper storage and handling of each vaccine. Specific directions for storage temperatures are stated in the vaccine product monograph or on the vaccine product label. Vaccine products issued under an Emergency Use Authorization (EUA) will have the storage information contained within the authorization.

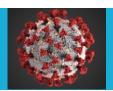
COVID-19 Vaccination Reminders

Many pharmacies and healthcare organizations have internal systems they use for vaccine recipient notifications and reminders. These Providers are encouraged to utilize these systems for upcoming dose series reminders to vaccine recipients. DPH will implement a statewide reminder recall program to support local efforts and provide additional redundancy for patient dose series reminder methods.

COVID-19 Vaccination Schedule – Primary Series

COVID-19 vaccination schedule for the primary series in the general population

Product	Authorized Age	Primary Series	Primary Series	Primary Series
	Groups		Dose Interval	Dose
Pfizer-BioNTech	5 through 11 years	2 doses	3 weeks	0.2 mL
Pfizer-BioNTech	12 years and older	2 doses	3-8 weeks	0.3 mL
Moderna	18 years and older	2 doses	4-8 weeks	0.5 mL
Janssen (J&J)	18 years and older	1 dose	N/A	0.5 mL



COVID-19 vaccination schedule for the primary series for people moderately or severely immunocompromised

Product	Authorized Age	Primary	Interval between	interval between 2 nd	Primary Series
	Groups	Series	1 st and 2 nd dose	and 3 rd dose	Dose
Pfizer-	5 through 11 years	3 doses	3 weeks	≥ 4 weeks	0.2 mL
BioNTech					
Pfizer-	12 years and older	3 doses	3 weeks	≥ 4 weeks	0.3 mL
BioNTech					
Moderna	18 years and older	3 doses	4 weeks	≥ 4 weeks	0.5 mL
Janssen (J&J)	18 years and older	1 dose	4 weeks	N/A	0.5 mL
		followed			
		by mRNA			

Additional Dose Considerations for Moderately to Severely Immunocompromised People

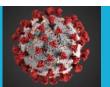
CDC recommends that people who are moderately to severely immunocompromised receive an additional dose of an mRNA COVID-19 Vaccine (Pfizer or Moderna) at least 28 days after completion of the initial two dose mRNA vaccine series. People who are moderately to severely immunocompromised should receive and additional dose of mRNA COVID-19 vaccine at least 28 days after completing one dose of Janssen vaccine.

For persons requesting an additional dose for a moderately to severely immunocompromised condition that person must provide documentation of an immunocompromising condition from their physician OR self-attest to one of the eligible immunocompromising conditions below by signing the consent form.

Moderately or severely immunocompromised persons aged ≥5 years (Pfizer-BioNTech recipients) or ≥18 years (Moderna recipients) should receive an additional primary dose of the same mRNA COVID-19 vaccine administered for the primary series ≥28 days after completion of the initial 2-dose series.

Eligible Immunocompromising Conditions for Additional Dose of COVID-19 Vaccine:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of a solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory



Additional Dose Considerations for Eligible Immunocompromised Populations:

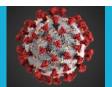
- 1. For those aged 5 through 11 years, if primary COVID-19 vaccination was completed with Pfizer mRNA vaccine product) and the recipient meets requirements for an additional dose, a third dose of Pfizer vaccine can be provided 28 days after the last dose.
- 2. For those aged 12 through 17 years, if primary COVID-19 vaccination was completed with Pfizer mRNA vaccine product and the recipient meets requirements for an additional dose, a third dose of Pfizer vaccine can be provided 28 days after the last dose.
- 3. For those aged 18 years and over, if primary COVID-19 vaccination was completed with either mRNA vaccine product (Moderna or Pfizer) and the recipient meets requirements for an additional dose, a third dose can be provided 28 days or more after the last dose of the primary series (If Moderna is used, a full dose of vaccine should be used for the additional dose).
- 4. If the primary COVID-19 vaccine series was completed with Janssen vaccine, an additional vaccine dose of mRNA COVID-19 vaccine should be given at least 28 days later.
- 5. Guidance for immunocompromised even after vaccination is to practice social distancing and masking. Close contacts of immunocompromised persons should be strongly encouraged to be vaccinated.

COVID-19 Vaccine Boosters

For individuals presenting for a booster dose, verify which primary vaccine series the individual received. If the primary series was completed with Pfizer-BioNTech or Moderna COVID-19 vaccines, booster doses can be given if it has been at least 5 months since the primary series was completed. If the primary series received was Janssen COVID-19 vaccine, booster doses can be given if it has been at least 2 months since the primary series was completed. In most situations, Pfizer BioNTech or Moderna COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for booster vaccination regardless of which vaccine was used for the primary series. Vaccine recipients should be advised of this but should be provided the COVID-19 vaccine of their choice. COVID-19 booster shots are the same formulation as the current COVID-19 vaccines. However, the Moderna COVID-19 vaccine booster shot is half the dose of the vaccine received in primary doses.

Pfizer-BioNTech Booster Doses:

- Individuals aged 12 years and older (including those aged 11 at the time of the primary series) should receive a booster dose of COVID-19 vaccine at least 5 months after the last dose was administered.¹
- 2. People ages 50 years and older may choose to receive a second booster dose using an mRNA vaccine if it has been at least 4 months after the first booster dose.



Moderna Booster Doses:

- 1. Individuals aged 18 and over who completed the Moderna vaccine series at least 5 months ago should receive a booster shot.
- 2. People ages 50 years and older may choose to receive a second booster dose using an mRNA vaccine if it has been at least 4 months after the first booster dose.

Johnson & Johnson/Janssen Booster Doses:

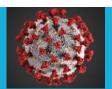
- Individuals aged 18 and over who received a single-dose primary Janssen COVID-19 should receive a single booster dose of COVID-19 vaccine if it has been at least 2 months following the primary dose. An mRNA COVID-19 vaccine is preferred over the Janssen COVID-19 Vaccine for booster vaccination.¹
- 2. People ages 50 years and older may choose to receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the first booster dose.

Heterologous ("mix and match") Booster Doses:

- 1. All available FDA authorized COVID-19 vaccines can be provided as a heterologous (or "mix and match") booster dose in eligible individuals following completion of primary vaccination with a different available COVID-19 vaccine.
- 2. The clinical considerations for heterologous mixing:
 - a. Eligible individuals may choose which vaccine they receive as a booster dose. Some people may prefer the vaccine type that they originally received, and others may prefer to get a different booster. CDC's recommendations now allow for this type of mix and match dosing for booster shots.
 - b. Heterologous dosing may be considered for the booster dose only. If Moderna is used for a booster dose, use the half dose shot for the booster (e.g., 0.25mL)
 - c. Individual benefit-risk assessment may inform which booster product to use.

Moderately or Severely Immunocompromised Booster Doses:

- 1. Moderately and severely immunocompromised people aged ≥12 years who initiated vaccination with an mRNA COVID-19 vaccine should receive a booster dose at least 3 months after the third dose in the primary series, for a total of 4 doses, preferably with an mRNA COVID-19 vaccine.
- Moderately and severely immunocompromised people ages ≥12 may choose to receive a second booster dose using an age-appropriate mRNA vaccine if it has been at least 4 months after the first booster dose, for a total of 5 doses.
- 3. Moderately and severely immunocompromised people aged ≥18 years who initiated vaccination with Janssen COVID-19 vaccine should get a booster dose at least 2 months after the second



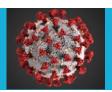
- (additional dose), for a total of 3 doses (1 Janssen vaccine dose followed by 1 additional mRNA vaccine dose, then 1 booster dose, preferably with an mRNA COVID-19 vaccine.
- 4. Moderately and severely immunocompromised people aged ≥18 years who initiated vaccination with Janssen COVID-19 vaccine may choose to receive a second booster dose using an mRNA COVID-19 vaccine if it has been at least 4 months after the first booster dose, for a total of 4 doses.
- 5. If a moderately or severely immunocompromised person aged ≥12 years has received two primary mRNA vaccine doses but has not yet received an additional mRNA primary dose, they should first receive the additional age-appropriate primary dose (at least 28 days after the second dose), followed by a single age- appropriate COVID-19 vaccine booster dose (at least 3 months after the additional primary dose). For people 12-17 years of age, the age appropriate COVID-19 primary series and booster dose can only be with the Pfizer BioNTech vaccine. For people ≥ 18 years of age, if Moderna is used for the booster, a dose of 100 ug (0.5 mL) should be used for the additional primary dose and 50 ug (0.25 mL) should be used for the booster dose.
- 6. People who inadvertently received the booster dose before their third primary dose, regardless of type of vaccine received as the booster dose, administer a Pfizer-BioNTech vaccine or a Moderna vaccine 100 μ g (0.5 mL) as the fourth dose (third primary) at least 3 months after the third dose.
- 7. People who initiated vaccination with Janssen COVID-19 Vaccine and may have received a booster dose (Pfizer-BioNTech, Moderna [50 µg], or Janssen vaccine), without having had the second (additional) mRNA vaccine dose. In this situation, regardless of type and timing of vaccine received as the second dose, administer a Pfizer-BioNTech vaccine or a Moderna vaccine 100 µg (0.5 mL) as the third (additional) dose at least 2 months after dose 2.
- 8. Currently, a booster dose is not recommended in people aged <12 years.

COVID-19 Vaccination Program Communication

Communication plans have been established within the state DPH Crisis and Emergency Risk Communication (CERC) plan. The plan has been vetted, updated, and approved for use in emergencies with an all-hazards approach. The state DPH Division of Communications will lead coordination of communication efforts about vaccine development and availability.

COVID-19 Vaccine Safety Monitoring

DPH has a policy in place for reporting vaccine adverse events following immunization services. The Vaccine Adverse Event Reporting System (VAERS) policy is located in the GIP Manual (Chapter 4), accessible on the GIP website https://dph.georgia.gov/immunization-section/immunization-publications. Providers authorized to administer vaccines are required by law to report to VAERS any

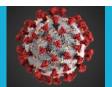


adverse event following immunization, including a vaccine administration error. GIP will include VAERS reporting procedure job aids and website information in provider training materials and resources.

COVID-19 vaccine recipients can also conduct vaccine safety monitoring via VSAFE. Providers must inform COVID-19 vaccine recipients about VSAFE. VSAFE is a new voluntary, smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins for COVID-19 vaccine recipients. V-safe allows vaccine recipients to report any side effects after administration of the COVID-19 vaccination to CDC in almost real-time. It also gives vaccine recipients a convenient reminder to complete their COVID-19 vaccine series at the appropriate time. Additional information may be found at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

COVID-19 Vaccination Program Monitoring

DPH will assume responsibility for continuous monitoring for vaccine-related situational awareness throughout COVID-19 vaccination response activities. To do so, DPH has developed a "COVID-19 Vaccine Program Provider Accountability and Waste Avoidance Policy" and a "COVID-19 Vaccine Fraud Policy", with corresponding acceptance agreements. With the "Georgia Department of Public Health Administrative Order for Public Health Control Measures," DPH has orderd Program Providers to comply with the policies subject to penalties and/or corrective action.



Section 1: COVID-9 Vaccination Preparedness Planning

Introduction

A safe and effective COVID-19 vaccine is a critical component in reducing COVID-19 related illnesses, hospitalizations, and deaths, and will help restore a sense of normalcy nationally. DPH understands the development of a successful COVID-19 vaccination program requires a strong partnership among federal, state, and local clinical and non-clinical partners. Through these established partnerships and following guidance from the Centers for Disease Control and Prevention (CDC), DPH is working to assure vaccines are distributed equitably and efficiently across Georgia.

The H1N1 pandemic demonstrated that well planned and executed large scale vaccination efforts are an effective method for addressing and slowing the spread of disease resulting from a naturally occurring pandemic. DPH developed the statewide COVID-19 vaccine administration and distribution plan using several resources, including best practices learned from past H1N1 pandemic response activities, the Georgia "DPH Pandemic Response Plan – Support Annex K: Mass Vaccination Distribution Plan," the CDC's "COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations," and other pandemic influenza planning guidance and tools. Understanding this is a situation that continues to evolve, DPH will review, update, and share revised versions of this plan as additional information is received and process improvements are identified.

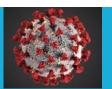
Purpose

This statewide Mass Vaccination Distribution and Administration Plan will be used as a state protocol for distributing and administering the COVID-19 vaccine to public health districts and other enrolled COVID-19 pandemic vaccine providers. In combination with the GIP Manual, Mass Vaccination Section, this plan will serve as the framework and guidance for districts and counties to create their detailed plans, which should be tailored to meet the needs of individual communities.

Lessons Learned from H1N1

Lessons learned from DPH's H1N1 vaccination response will be used to inform the COVID-19 vaccination response. Some of these key lessons include:

- Vaccine supply and availability may be sporadic in the initial phases of a pandemic response.
- DPH must be able to scale down plans based on the degree of community spread.
- Communication with providers is as essential as communication with staff.
- Staff cross-training is essential.
- The "push" method of vaccination was more effective during this event than the "pull" method. That is, a higher portion of the population was served by establishing mass vaccination clinics in



popular, high traffic areas instead of holding the clinics in geographically unfamiliar clinical settings.

- Collaboration with the Department of Education provided for a higher rate of vaccination in Georgia's population.
- Full-scale mass vaccination sites would be more effective with additional human resources.
- Need to be flexible and recognize the variability that is inherent in pandemics and to be able to plan and respond accordingly

Section 2: COVID-19 Organizational Structure and Partner Involvement

Local and state agencies and organizations have specific roles and responsibilities during public health emergencies. A complete list of these roles and responsibilities can be found within the DPH, Emergency Preparedness and Response (EPR) Emergency Operations Plan (EOP). The EOP defines the roles and responsibilities related to mass vaccination distribution and administration response efforts.

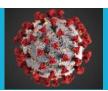
Partner Involvement

Core COVID-19 Vaccination Planning Team Members

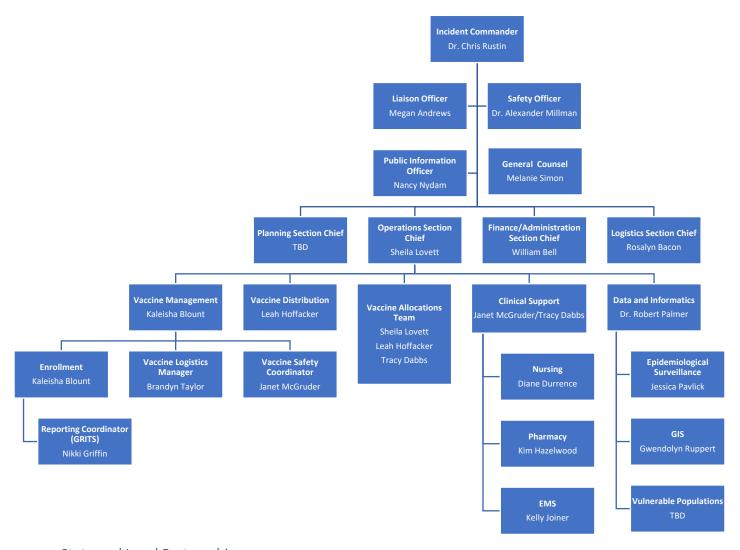
DPH has established a COVID-19 Vaccine Core Planning and Coordination Team (COVID-19 Team). The COVID 19 Team will be responsible for the annual review of state plans, updating plans during an active response, and distributing updated plans to partners and stakeholders.

A complete list of the COVID-19 Team members is found in Appendix B. The Team membership may be revised throughout this response. In addition to DPH's Immunizations and Emergency Preparedness staff, representation from each of the following offices are active participants of this team:

- Office of General Counsel: Office of General Counsel will provide legal guidance and counsel and assist in applying and adhering to federal and state laws and regulations throughout the incident. Please see the Disease Exposure Control Plan (DEC), DPH EOP, Annex P
- Office of Emergency Medical Services and Trauma (EMS): EMS will communicate training requirements, information, data reporting requirements, etc., to EMS services throughout the state via the Regional EMS Directors.
- Office of Nursing (OON): OON will coordinate with County Nurse Managers and district Nursing Directors throughout the state to assure appropriate staffing of Mass Vaccination Clinics (MVC).
- Office of Pharmacy: Pharmacy will collaborate with the districts and support the Pharmacy
 Disaster Response Coordinator pharmacist as outlined under Roles and Responsibilities in the
 DPH, EOP.



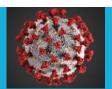
GDPH's COVID-19 Vaccine Core Planning & Coordination Organizational Chart



State and Local Partnerships

Collaboration between state and local public health, other state agency partners, private immunization providers, and immunization stakeholders is key to vaccine response efforts. A comprehensive list of crucial collaborating partners for this response activity is included in Appendix B. This list may be updated as additional collaborations are established.

DPH has identified staff to serve as primary and back-up for each of the roles outlined here. Each district will identify primary and back-up staff members responsible for each position:



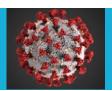
- Vaccine Safety Coordinator: Assure public health staff is trained on the proper administration, storage, and handling of the vaccine. Also, train on treating adverse events and reporting them through the Vaccine Adverse Event Reporting System (VAERS) on-line.
- Reporting Coordinator: Contact for reporting responsibilities as determined per state/federal
 requirements. The assumption should be that all doses administered will be submitted (via an
 interface or direct entry) into the Georgia Registry of Immunization Transactions and Services
 (GRITS).
- Medical Countermeasures Coordinator: Manages and coordinates receipt of supplies and medications at the Receive, Stage and Store Warehouse (RSS). Recruits and supports closed Point(s) of Distribution (POD) and MVC partners throughout their enrollment and administration activities.
- Vaccine Logistics Manager: Documents vaccine supply and inventory and coordinates shipments to other sites, if needed.

Tribal Communities

Collaboration with federally and state-recognized tribal communities is essential for reaching one of this response's priority populations. While Georgia has no federally recognized tribes or Indian Health Service tribal (HIS) facilities within the state, response outreach will center on state-recognized tribes that are primarily informally organized. GIP has reached out to local tribal organizations for collaborative activities and will continue to make inroads to sustainable immunization partnerships.

There are no healthcare organizations primarily serving American Indian individuals in Georgia. Most tribal members are not concentrated on reservations, contributing to challenges faced when working to assess population estimates for this priority group. For example, one of Georgia's three tribal groups only has one member living within Georgia. In contrast, the other members cross back and forth across the Georgia/Florida state line, living primarily in Florida. GIP will continue efforts to gather the number of populations served in tribal communities, as well as assess need and resources available to establish MVCs/PODs within these areas using the following methods:

- Work with regional health districts, local health departments, and tribal councils to gather data
 on the number of tribal members to estimate better the number of vaccines needed to support
 this population.
- Continue to support district and local county health departments with COVID-19 vaccine educational and vaccination outreach efforts targeting this population in the absence of tribal medical facilities.
- Continue to support private vaccination providers with COVID-19 vaccination and vaccine educational outreach serving Georgia's Native American populations and other rural populations.



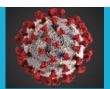
 Continue to reach out to tribal partners, solidify connections with local tribal leaders, and support tribe-originated needs for the COVID-19 vaccine.

Roles and Responsibilities

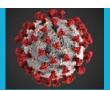
DPH Planning and Coordination Team (The Team)

The PH COVID-19 Vaccine Core Planning and Coordination Team (the Team) will be responsible for the annual review of state plans, updating plans during an active response, and distributing updated plans to partners and stakeholders. Primary responsibilities of this core team include:

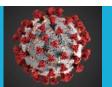
- Assuring Mass Vaccination Distribution and Administration Plan is in alignment with the current version of the GIP Manual and Nursing Protocols and current federal guidance so that all resources communicate a consistent message;
- Using cross-team collaboration (emergency preparedness, immunization, pharmacy, nursing, communications, and field operations) in the development of plans, protocols, and guidance;
- Determining and communicating the eligible populations based on Emergency Use
 Authorization (EUA) guidance, Advisory Committee on Immunization Practices (ACIP)
 recommendations, and CDC guidelines, contingent upon current issues and available guidance
 relative to those issues.
 - FDA authorized an EUA for the Pfizer-BioNTech COVID-19 vaccine on December 11, 2020, https://www.cdc.gov/vaccines/covid-19/eua/index.html. The CDC's ACIP released interim recommendations for the vaccine on December 12, 2020. https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm.
 - Update: FDA expanded the EUA to include ages 12 15 years old on May 10, 2021.
 - Update: FDA authorized full licensure for Pfizer-BioNTech COVID-19 vaccine on August 23, 2021 for 16 years of age and over; the first mRNA COVID-19 fully licensed vaccine in the United States, which will now be marketed as Comirnaty.
 - Update: CDC's ACIP released interim recommendations for additional doses of Pfizer-BioNTech COVID-19 vaccine on August 13, 2021 for moderately to severly immunocompromised individuals.
 - Update: FDA authorized an EUA for Pfizer-BioNTech COVID-19 Vaccine Booster Shots on September 22, 2021 for individuals who are 18 years of age and over who meet the recommended criteria.
 - 65 years and older
 - Age 18+ who live in long-term care settings
 - Age 18+ who have underlying medical conditions



- Age 18+ who work or live in high-risk settings
- Update: FDA expands emergency use authorization of the Pfizer-BioNTech COVID-19 Vaccine to include children 5 through 11 years of age on October 29, 2021.
- Update: CDC's ACIP released interim recommendations for use of the Pfizer-BioNTech COVID-19 vaccine in children aged 5-11 years on November 2, 2021.
- Update: CDC's ACIP released emergency use instructions (EUI) on November 17,
 2021 to include:
 - Certain moderately and severely immunocompromised persons aged 12 years and older, who completed a primary series of non-FDA authorized or approved COVID-19 vaccines, are eligible to receive a single additional primary series dose of the COVID-19 vaccine by Pfizer-BioNTech.
 - Certain adults aged 18 years and older, who have completed a primary series of a non-FDA authorized or approved COVID-19 vaccine, are eligible to receive a single booster dose of the COVID-19 vaccine by Pfizer-BioNTech.
- Update: FDA expands eligibility for COVID-19 vaccine boosters to vaccine recipients ages 18 years and older after completion of primary vaccination on November 19, 2021.
- Update: CDC's ACIP expands recommendations for COVID-19 vaccine booster doses to include all adults ages 18 years and older, who have received a mRNA COVID-19 vaccine at least 6 months after receiving the second dose of the primary series.
- Update: CDC's ACIP expands recommendation for COVID-19 vaccine booster doses to include adolescents ages 12 to 17 years old should receive a booster shot 5 months after their initial Pfizer-BioNTech vaccination series.
- Update: On January 4, 2022, CDC updated its recommendation for booster shot intervals for the Pfizer-BioNTech COVID-19 Vaccine, shortening the interval from 6 months to 5 months for ages 12 years and over.
- Update: On April 21, 2022, CDC updated its recommendation to include the administration of a second booster dose of COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizwer-BioNTech COVID-19 Vaccine at least 4 months after receipt of a first booster dose of any FDA authorized or approved COVID-19 vaccine to individuals 50 years of age and older; individuals 12 years of age or older who are moderately or severely immunocompromised; and individuals ages 18 years and older who received Janssen COVID-19 Vaccine as both a primary and a booster dose.

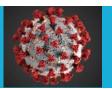


- FDA authorized an EUA for Moderna COVID-19 vaccine on December 18, 2020, https://www.modernatx.com/covid19vaccine-eua/. The CDC's ACIP released interim recommendations for the vaccine on December 20, 2020.
 https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm
 - Update: CDC's ACIP released interim recommendations for additional doses of Moderna COVID-19 vaccine on August 13, 2021 for moderately to severly immunocompromised individuals.
 - Update: FDA amended the EUA to allow for a single booster dose of Moderna COVID-19 vaccine on October 20, 2021.
 - 65 years and older
 - Age 18+ who live in long-term care settings
 - Age 18+ who have underlying medical conditions
 - Age 18+ who work or live in high-risk settings
 - Update: Following this EUA amendment, CDC's ACIP recommended a single booster dose of Moderna COVID-19 vaccine six months after completion of the primary two-dose series of Moderna vaccine on October 21, 2021. A single booster dose is recommended for the following individuals:
 - 65 years and older
 - Age 18+ who live in long-term care settings
 - Age 18+ who have underlying medical conditions
 - Age 18+ who work or live in high-risk settings
 - Update: FDA expands eligibility for COVID-19 vaccine boosters to vaccine recipients 18 and older after completion of primary vaccination on November 19, 2021.
 - Update: CDC's ACIP expands recommendations for COVID-19 vaccine booster doses to include all adults ages 18 years and older, who have received a mRNA COVID-19 vaccine at least 6 months after receiving the second dose of the primary series.
 - Update: On January 7, 2022, FDA amends the emergency use authorization (EUA) for the Moderna COVID-19 Vaccine to shorten the interval between the completion of a primary series of the vaccine and a booster dose to at least 5 months for individuals 18 years of age and older.
 - Update: On January 7, 2022, CDC updated its recommendation for booster shot intervals for the Moderna COVID-19 Vaccine, shortening the interval from 6 months to 5 months for ages 18 years and over.
 - Update: On April 21, 2022, CDC updated its recommendation to include the administration of a second booster shot for the SPIKEVAX (COVID-19 Vaccine, mRNA) or Moderna COVID-19 Vaccine at least 4 months after receipt of a first booster dose of any FDA authorized or approved COVID-19 vaccine to



individuals 50 years of age and older; and individuals 18 years of age or older who are moderately or severely immunocompromised; and individuals ages 18 years and older who received Janssen COVID-19 Vaccine as both a primary and a booster dose.

- FDA authorizes an EUA for Janssen (Johnson & Johnson) on February 27, 2021 for adults ages 18 and over.
 - Update: FDA amended the EUA to allow for a single booster dose of Janssen COVID-19 vaccine on October 20, 2021. Following this EUA amendment, CDC's ACIP recommended a single booster dose of the Janssen (Johnson and Johnson) COVID-19 Vaccine administered at least 2 months after completion of the single-dose primary regimen to individuals 18 years of age and older.
 - Eligible individuals may choose which vaccine they receive as a booster dose. Some people may have a preference for the vaccine type that they originally received and others, may prefere to get a different booster. CDC's recommendations now allow for this type of mix and match dosing for booster shots.
- Communicating vaccination planning efforts and priority population specifications to the Governor, legislators, medical societies, other state agencies, state-level provider organizations, and other stakeholders as needed:
- Providing guidance and technical support on planning for COVID-19 vaccine-related activities to district and local public health partners and all other COVID-19 pandemic providers;
- Engaging and facilitating registration of statewide provider networks, such as chain pharmacies, hospitals, long-term care facilities, correctional facilities, primary care providers, pediatricians and other other potential vaccination providers.
- Providing training on vaccine storage and handling, data submission to GRITS, and adverse event reporting to non-public health providers. Conduct train-the-trainer sessions with identified public health district personnel for continued training of local-level public health staff;
- Developing a method for allocating vaccines to each public health district and other providers, which will depend on population density, level of disease endemic to each district, and the number of priority populations;
- Coordinating the direct distribution of vaccine to each district or county public health provider and registered non-public health providers with approved vaccine storage units and capacity;

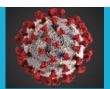


- Using the proper method of cold chain transport when assisting with vaccine transport between vaccinating sites;
- Planning for receiving and reporting aggregate data back to the CDC through GRITS generated reporting mechanisms;
- Providing social distancing guidance for vaccination operations following the state Disease
 Exposure Control (DEC) plan and current CDC guidelines for the protection of staff and those
 participating in the vaccination campaigns;
- The DPH Communications Office will provide key guidance and talking points and disseminate public service announcement language to support statewide campaigns; and
- Providing guidance to key state partners working with vulnerable populations.

DPH District Responsibilities

Public Health Districts have developed plans to utilize Points of Distribution for Medical Countermeasures and Administration and Medical Materiel Management and Distribution. Public Health districts are to utilize Points of Distribution (PODs) as Mass Vaccination Clinics (MVCs) for the SARS-CoV2 (COVID-19) mass vaccination campaigns. Primary responsibilities include:

- Develop a COVID-19 Mass Vaccination Distribution and Administration Plan following state guidance that best meets each community's needs within its geographical boundaries, maximizing efficiency in the use of resources.
- Engage and encourage registration of partner providers to assist in vaccinating all priority populations.
- Collaborate with community partners (local colleges, schools, and/or large childcare facility personnel) to assure access to vaccination for priority populations.
- Develop and implement closed MVCs for vaccination clinics, as staffing and other resources allow.
- Explore other nontraditional venues for vaccine administration, such as retail settings, faith-based facilities, and occupational settings.
- Comply with all reporting requirements, including interim reports of vaccination planning and implementation activities specific to each event.
- Each district or county will have agreements and contracts with the local police department to help secure vaccines and maintain order at mass vaccination sites. Emergency Response plans will be in place at each location.
- Districts will have standing operating procedures (SOPs) for each vaccination site. The CDC recommends facilities develop and maintain written, detailed, and up-to-date storage and handling SOPs. SOPs should be reviewed by all staff and updated by the vaccine coordinator. SOPs should contain plans and information for three major areas:



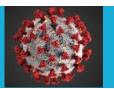
- General information include contact information for vaccine manufacturers, equipment service providers, and essential facility staff, as well as job descriptions, regularly used forms, and staff training requirements.
- Routine storage and handling include information for all aspects of vaccine inventory management, from ordering to monitoring storage conditions.
- Emergency vaccine storage, handling, and transport outline the steps to be taken in the event of equipment malfunctions, power failures, natural disasters, or other emergencies that might compromise vaccine storage conditions.
- Adhere to storage and return guidelines for manufactures' thermal shippers.
 - Pfizer: https://contlogo.s3.eu-central-1.amazonaws.com/Pfizer/Thermal%20Shipper%20Return%20Guidance.pdf
 - Video: https://www.cvdvaccine-us.com/product-storage-and-dry-ice
 - Moderna:
 https://eziz.org/assets/docs/COVID19/2020DecMcKessonVaccineShipperReturnInstructions.pdf

More details regarding the development of SOPs are available in the CDC's Vaccine Storage and Handling Toolkit: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

- Each Public Health MVC will obtain informed consent for every patient before vaccination.
- Each public health district/county health department/partner provider will have access to and distribute the COVID-19 EUA Fact Sheet or Vaccine Information Statement (VIS) document before administering each vaccine, following federal law.
- Every provider's responsibility is to obtain and distribute an approved EUA and VIS, as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representatives via electronic or printed materials.
- Each district is responsible for the advertising of <u>eligible populations</u> and sites of the PODs/MVCs.

Section 3: Phased Approach to COVID-19 Vaccination

Throughout this response, the main goal is to assure vaccine distribution and administration processes are in place to rapidly administer vaccines to Georgia residents. Early assumptions included a possible imbalance between vaccine demand and supply. Provider sites and vaccine shipments were prioritized according to the populations those providers serve and the key populations who have been prioritized for the vaccination effort. Initially, key populations were prioritized using a phased approach based on assessed level of risk for exposure to or complications from the disease.



As of May 2021, all residents of Georgia ages 5 and over are eligible to receive the COVID-19 vaccine. Vaccine supply currently exceeds demand, allowing DPH to focus distribution efforts on identifying vaccine deserts to improve vaccine access across Georgia, with a special focus on our underserved populations. DPH continues to expand vaccination efforts to increase uptake for initial vaccine doses, boosters, and additional doses following FDA, CDC, and ACIP recommendations and guidance.

Update: As of August 2021, all residents of Georgia ages 12 to 15 years of age are eligible to Pfizer BioNTech COVID-19 Vaccine.

Update: As of November 2021, all residents of Georgia ages 5 to 11 years of age are eligible to Pfizer BioNTech COVID-19 Vaccine.

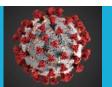
Situation

Initially, DPH received allocations of COVID-19 vaccines from the federal government. The vaccine was distributed using the current Vaccines for Children (VFC) vaccine distribution infrastructure. This distribution mechanism allows vaccines to be shipped directly to providers who have enrolled as COVID-19 vaccine providers. Federal allocations were listed, June 2021. However, the process for vaccine ordering and distribution continues to be processed following this same method. If a provider cannot store or administer minimum shipping quantities during the designated time frame, DPH will provide vaccines for these sites through an approved redistribution location. As an additional backup to the VFC distribution method, vaccine suppy is sent to Georgia's Receipt Stage and Store (RSS) warehouse (location will not be disclosed in the plan due to security).

Program Continuous Monitoring

DPH's main goal is to assure vaccine distribution and administration processes are monitored to assure equitable vaccine distribution in access across the state. Vaccine supply amounts are at levels greater than demand. Supply levels are closely monitored and DPH will reinstate a vaccine allocation model should the need arise. Currently, provider orders are reviewed, confirmed, and processed upon once per week.

For mass vaccination, the state followed recommendations from the ACIP. These recommendations are the most current guidelines regarding vaccine administration, storage and handling, and safety. The ACIP details guidance for the administration of all routinely administered vaccines. Recommendations for each vaccine are updated as needed. Current copies of recommendations of the ACIP for each vaccine are located on the following CDC website: https://www.cdc.gov/vaccines/covid-19/info-by-product. Each public health facility that administers vaccines must have a written copy of the ACIP recommendations or internet access to the above website.



DPH also disseminates recommendations and guidance via the GIP Manual. This manual provides guidance for routinely ordering, storing, handling, and administering vaccines and providing immunization related services. The manual also includes quality assurance standards and standard operating guidelines for conducting mass vaccination clinics (MVCs). The manual is updated at least annually and can be accessed at https://dph.georgia.gov/immunization-publications. Georgia Public Health districts may use Point of Distribution (POD) locations and plans to conduct MVCs.

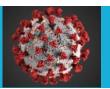
Possession of Vaccines

In addition to the enrollment requirements included in Section 5 of this plan, Providers must meet "one" of the following legal requirements to receive vaccine shipments:

- Must be able to possess dangerous drugs following O.C.G.A.§ 16-13-72 and must meet the definition of "pharmacist" or "pharmacy" as defined by O.C.G.A. § 26-4-5(28) or as defined by O.C.G.A § 26-4-5(30).
- Must be able to possess dangerous drugs following O.C.G.A § 16-13-72 and must meet the
 definition of "practitioner" or "practitioner of the healing arts" as defined by O.C.G.A. § 26-45(33).
- A nurse acting pursuant to an influenza vaccine protocol agreement as provided by O.C.G.A. §
 43-34-26.1 and meets the definition of a "nurse" as defined in 43-34-261 (a) (7). "The nurse (RN or LPN) must be regularly employed by a physician who is actively employed in private practice."
- Must be able to possess dangerous drugs following O.C.G.A § 16-13-72 and meet the definition of "advanced practice registered nurse" as defined by O.C.G.A.§ 43-34-25 and acting pursuant to an influenza vaccine "protocol agreement" following O.C.G.A.§ 43-34-25.
- Must be able to possess dangerous drugs as defined by O.C.G.A. § 16-13-72 and meet the requirements of O.C.G.A. § 43-34-103, meet the definition of "Physician Assistant" as defined by O.C.G.A. §43-34-102 and be acting pursuant to an influenza vaccine "job description" following O.C.G.A. §43-34-102.

Authority to Vaccinate during a Public Health Emergency

- Under Georgia law and, an Executive Order issued by Governor Brian Kemp, or the federal PHEP act, the following health professionals are authorized to administer vaccines:
 - Physicians O.C.G.A. § 43-34-21, et. seq.
 - Pharmacists O.C.G.A. § 26-4-4, 26-4-5(30)(A) and (31), O.C.G.A. §43-34-26.1
 - <u>Certified Emergency Medical Technicians</u> O.C.G.A. § 31-11-53
 - Paramedics O.C.G.A. § 31-11-54
 - Certified Cardiac Technicians O.C.G.A. § 31-11-55
 - Dentists O.C.G.A. § 43-11-1 (6) and § 43-11-17 Executive Order June 30, 2021.02
 - Certified Medical Assistants - O.C.G.A. § 43-34-44; Executive Order June 30, 2021.02



- <u>Licensed Practical Nurse (LPN)</u> O.C.G.A. § 43-26-3(6) and § 43-34-23(a)(7) Executive Order June 30, 2021.02
- Retired Nurses Executive Order June 30, 2021.02
- Registered Professional Nurse (RN) O.C.G.A. § 43-26-3(6) and (8), O.C.G.A. § 43-34-26.1(c) and O.C.G.A. § 43-34-23(a)(6 8) and (b)(2)
- Advanced Practice Nurses: Certified Nurse Midwife, Certified Registered Nurse
 Anesthetist, Nurse Practitioner, and Clinical Nurse Specialist O.C.G.A. § 43-26-3(1),
 (6) and (8) and § 43-34-23(b)(1)(B)
- Physician Assistant (PA) O.C.G.A. § 43-34-105 and O.C.G.A. §43-34-23(b) (1-2) Executive Order June 30, 2021.02
- Medical Student, Intern or Resident O.C.G.A. § 43-34-22(b)(9)(A) and O.C.G.A. § 43-34-26(a)(3)

The Code does not give the following professionals authority to administer COVID vaccines and no such authority has been given to them by Executive Order:

- Acupuncturists O.C.G.A. § 43-34-62 (1) and (4)
- <u>Veterinarians</u> O.C.G.A. § 43-50-3 (5)
- <u>Chiropractors</u> O.C.G.A. § 43-9-1 (2)

The U.S. Department of Health and Human Services has issued an emergency declaration allowing pharmacists and pharmacist interns to become "covered persons" under the Public Readiness and Emergency Preparedness Act (PREP Act). To read more about the PREP Act and this emergency declaration, please visit https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx.

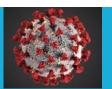
Vaccine Program Implementation Phases

Phase 1: Limited COVID-19 Vaccine Availability

COVID-19 vaccine supply was limited during the initial implementation of vaccine response activities (Phase 1). During this phase, vaccine efforts focused on reaching defined critical populations who met DPH defined Phase 1 criteria. Vaccine administration occurred through vaccination sites, including, but not limited to, public health clinics, hospitals, long term care facilities (LTCFs), emergency medical services (EMS), private providers, pharmacies, etc.

The below list of Phase 1 populations is not all-inclusive:

- 1. Healthcare personnel likely to be exposed to or treat people with COVID-19
- 2. First Responders
- 3. People at increased risk for severe illness from COVID-19, including those 65 years of age and older'; and



4. Staff and residents of Long Term Care Facilties;

Initial vaccine supply was not enough to maximize access for the entire Phase 1 population. ACIP recommended that healthcare personnel be prioritized in the earliest phase of COVID-19 vaccination (https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm). However, in settings where the initial vaccine supply was insufficient to vaccinate all healthcare providers, sub-prioritization of vaccine doses was implemented. Considerations for sub-prioritization of equal importance included but were not limited to:

- 1. Phase 1-A+ included paid and unpaid persons serving in a healthcare setting with the potential for direct or indirect exposure from patients or infectious materials. Hospital staff, public health clinical staff, EMS, and other first responders, long term care facility (LTCF) staff, and urgent care facility staff are examples of people who are included in this Phase. Additional examples include:
 - a. Healthcare workers (e.g., physicians, nurses, pharmacists, EMS, laboratory staff, environmental services, etc
 - b. LTCF staff and residents
 - c. Adults 65 and older and their caregivers
 - d. Law enforcement, fire personnel (e.g., volunteer fire departments), dispatchers, 9-1-1 operators, etc.)
- 2. Eligible populations will be defined and added as more vaccine becomes available.

For more specific details on current eligible populations, please see Appendix C.

Phase 2: Increased COVID-19 Vaccine Availability

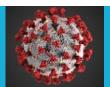
As vaccine availability increased, vaccine response efforts also expanded to assure vaccination of Phase 1 critical populations not yet vaccinated, as well as members of the population for whom vaccine was recommended.

Additional eligible populations were added on March 8, 2021.

These included:

- Adults with intellectual and developmental disabilities and their caregivers
- o Educators and staff (Pre-school, K-12, DECAL licensed or exempt childcare)
- Caregivers of Children with Medically Complex Conditions

Phase 3: Vaccine Supply Widely Available



COVID-19 vaccination activities transitioned to Phase 3 response, June 2021, once vaccines became widely available. Planning for this phase assumed that vaccine supply would exceed demand, and access to vaccines would be available through a variety of providers.

Current vaccine supply continues to exceed demand, and access to vaccines are available through over 2000 actively enrolled providers.

Phase 4: Recovery/Mitigation

The critical activities of recovery include, but are not limited to:

- 1. Assure accurate documentation of reported adverse events and doses administered.
- 2. Return surplus vaccine following federal guidelines.
- 3. Follow the Strategic National Stockpile (SNS) and Medical Countermeasures (MCM) Plans, as needed.
- 4. Document lessons learned and adjust vaccination plans based on lessons learned.

Mitigation minimizes the adverse impact of an emergency and reduces vulnerability to future emergencies. Mitigation measures may be implemented at any time. Mitigation includes:

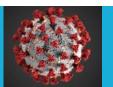
- 1. Continued vaccination campaigns to reduce the risk of infection;
- 2. Continued public information and education; and
- 3. Regular training and exercises to improve public health's ability to respond to future outbreaks and pandemics.

Based on available clinical trial data, COVID-19 vaccination may cause systemic post-vaccination symptoms, such as fever, headache, and muscle pain at the injection site. While the incidence and timing of post-vaccination symptoms will continue to be updated with available clinical data, strategies are needed to mitigate possible healthcare personnel absenteeism and resulting personnel shortages due to the occurrence of these post-vaccination symptoms. Considerations include:

- Staggering of delivery of the vaccine to healthcare personnel in a facility so that personnel from
 a single department or unit are not all vaccinated simultaneously. Based on greater
 reactogenicity observed following the second vaccine dose based on current clinical trial data,
 staggering considerations may be more critical following the second dose; and
- Planning for personnel to have time away from work if they develop systemic symptoms following a COVID-19 vaccination.

Section 4: Eligible Populations

During limited vaccine availability, GIP utilized CDC ACIP recommendations and the National Academy of Medicine's Framework for Equitable Allocation of COVID-19 Vaccine to identify, estimate the numbers



of, and locate critical populations for COVID-19 vaccine distribution. GIP used a combination of a) existing national, state-wide, and local data sources; b) engagement of community-based organizations, academic institutions, and state agencies and c) mapping, modeling and forecasting, and d) surveillance data. All information collected on critical populations (i.e., estimate and data source) was compiled into a Critical Populations (Appendix D) database maintained by DPH. In addition to DPH identifying, estimating, and locating critical populations, each of the 18 health districts were required to identify data sources to assess critical populations in their respective areas. The information from local public health was collected at the state-level and compared to state estimates.

As of May 2021, all residents of Georgia ages 5 and over are eligible to receive the COVID-19 vaccine. Vaccine supply currently exceeds demand, allowing DPH to focus distribution efforts on identifying vaccine deserts to improve vaccine access across Georgia, with a special focus on our underserved populations. DPH continues to expand vaccination efforts to increase uptake for initial vaccine doses, boosters, and additional doses following FDA, CDC, and ACIP recommendations and guidance.

Update: As of August 2021, all residents of Georgia ages 12 to 15 years of age are eligible to Pfizer BioNTech COVID-19 Vaccine.

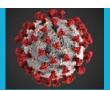
Update: As of November 2021, all residents of Georgia ages 5 to 11 years of age are eligible to Pfizer BioNTech COVID-19 Vaccine.

Data Sources

DPH established a list of currently available data sources that estimate the numbers of critical populations. The current data sources include, but are not limited to, the Cybersecurity and Infrastructure Security Agency (CISA), the U.S. Census, Medicare, and Medicaid. Additionally, Georgia's Online Analytical Statistical Information System (OASIS) is used to estimate and locate critical populations. OASIS is a suite of interactive tools used to access the Georgia Department of Public Health's standardized health data repository. Additional data sources are described below.

Partnerships

Professional Organizations/Societies, State Agencies, Academic Institutions,
 Licensing/Regulatory Boards, etc.: DPH has established relationships with professional
 organizations/societies, state agencies (e.g., Department of Community Health, Georgia
 Emergency Management Agency), academic institutions, and licensing/regulatory boards.
 DPH will work with these organizations and groups to gather their current data on specified
 critical populations.



- 2. Community-Based Organizations: Community-based organizations (CBOs) traditionally commit to locate and reach vulnerable populations to provide services while accommodating language, cultural, and accessibility needs. They offer day-to-day services and often have earned the trust of the individuals they serve. Hence, they can also provide an accurate barometer of needs and mobilize the community and local resources. DPH has established relationships with CBOs at both the state and local levels. The DPH will work closely with CBOs to identify the population they serve and collect current data on the specified population. Additionally, some CBOs have begun utilizing neighborhood or geographic information systems (NIS or GIS) to locate their target population. Therefore, DPH will work with CBOs to collect this data to find critical populations.
- **3. COVID-19 Health Equity Team**: In response to the pandemic, DPH has established a COVID-19 Health Equity Council. The team has been engaging CBOs to address health inequities exacerbated by COVID-19. DPH will utilize the current partnerships created by this team to collect estimates on critical populations and locate them.

Mapping, Modeling, and Forecasting

DPH partnered with academic institutions and GIS experts to conduct risk assessments to identify and categorize subset groups. Assessments included geospatial analysis, modeling, mapping communities, the burden of disease, access to testing, vaccine providers, and places of employment to identify groups at the highest risk for disease or severe illness and available resources. Additionally, DPH partnered with the Georgia Emergency Management Agency (GEMA) to map current vaccination providers to identify areas and communities where vaccination services are scarce.

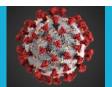
Surveillance Data

DPH will continue to analyze COVID-19 surveillance data to identify, estimate, and locate critical populations in Georgia. Analyzing surveillance data allows public health to identify vulnerable populations at the most significant risk for disease and more severe outcomes informing vaccine response strategies.

Defining Populations

DPH uses the U.S. Department of Homeland Security

(https://www.cisa.gov/sites/default/files/publications/Version 4.0 CISA Guidance on Essential Critica Infrastructure Workers FINAL%20AUG%2018v3.pdf) as guidance to define the essential critical infrastructure workforce. However, state officials will decide the final classification of a group as an essential critical infrastructure workforce in Georgia. To estimate the number of essential workers in Georgia, DPH utilizes a combination of, but not limited to, national (census), state, and local data sources, and data from professional organizations and licensing boards (Appendix D).



The definition of essential critical infrastructure workforce established by DPH was provided to key stakeholders including, but not limited to, local public health departments, healthcare providers, professional societies/organizations, pharmacists, academic institutionsetc.

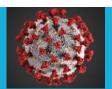
With sufficient vaccine supply now available, GA DPH utilizes <u>ACIP guidance</u>, pre-established, evidenced-based priority categories and definitions, and state-specific COVID-19 surveillance data to identify different subset groups of critical populations in Georgia. Considerations for identifying subset groups include, but are not limited to, occupational risk, the burden of disease, vulnerability to severe illness, residential setting (i.e., congregate), geographical location, and equity. To assure an equitable framework for vaccination distribution during limited vaccine availability, DPH considered the following criteria proposed by CDC and the National Academy of Medicine:

- **Risk of acquiring infection**: Higher priority given to individuals who have a greater probability of being in settings where COVID-19 is circulating and exposure to the virus.
- **Risk of severe morbidity and mortality**: Higher priority given to individuals with a greater probability of severe disease or death if they acquire infection.
- Risk of negative societal impact: Higher priority is given to individuals with societal function.
 Upon whom other people's lives and livelihood depend directly and would be imperiled if they fell ill. It does not consider their wealth or income or how readily an individual could be replaced in a work setting, given labor market conditions.
- **Risk of transmitting the disease to others**: Higher priority is given to individuals who have a higher probability of transmitting the disease.

Considering these factors, DPH worked with state officials to establish subset groups of critical populations. When a person appeared in more than one group, they were prioritized for vaccination in the highest Phase group in which they were included.

Additionally, DPH partnered with academic institutions to conduct risk assessments to identify and categorize subset groups. Assessments included geospatial analysis, modeling, mapping communities, disease burden, access to testing, and vaccine providers to identify groups at the highest risk for disease or severe illness and available resources.

Through COVID-19 disease surveillance and the development of COVID-19 guidance, the GA DPH has established relationships with academic institutions, government agencies, professional organizations, various industries (e.g., Georgia Chamber of Commerce, poultry plants, manufacturers, and warehouse distribution companies), healthcare organizations, jails, detention centers, employers, and community-based organizations (CBOs). To establish points of contact (POC) with critical populations, the DPH utilized existing relationships, state-based listservs, and POCs. Additionally, the established POCs and listservs are used to identify and engage supplementary POCs. DPH's COVID-19 Health Equity Team assists in identifying additional POCs, focusing primarily on CBOs. An up-to-date communication



distribution list of organizations, healthcare providers, agencies, and POCs is maintained throughout vaccine distribution to assure consistent communication with key stakeholders. When appropriate, essential COVID-19 vaccine information for critical populations is provided on the DPH website; health advisory notices, communication materials, and relevant updates for critical populations will be placed on DPH's webpage and updated as necessary.

Health Districts and Local Public Health Departments

Georgia's 18 Health Districts and local public health departments have established relationships with local community partners, healthcare organizations, long-term care facilities, businesses, industries, and professional organizations. Each district is required to establish POCs for key critical populations to a) identify and locate critical populations in their geographic area and b) communicate timely and effective COVID-19 vaccination messaging. Districts are required to complete a district-specific "Population Group Worksheet" (Appendix E) and submit the original and any updates to DPH.

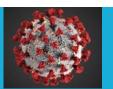
Section 5: COVID-19 Provider Recruitment and Enrollment

In partnership with Emergency Preparedness, GIP began the first phase of COVID-19 provider recruitment on August 12, 2020, by disseminating recruitment letters to external partners; Health Districts, currently enrolled Vaccines for Children (VFC) providers, and previous H1N1 mass vaccination providers. Each letter was tailored to address further recruitment instructions based on provider type and provided a link for providers to complete a *COVID-19 Vaccine Pre-Enrollment Questionnaire* through survey monkey was provided.

The recruitment process has now moved to an online enrollment process on GRITS. The process includes a review of submitted applications to confirm providers meet federal requirements. GIP enrollment staff assess providers' ability to store and handle vaccines with documented completed training, through a review of their submitted application followed by the completion of an enrollment site visit facilitated by their assigned Immunization Regional Consultant (IRC). GIP initially uses a phased approach to enroll providers in the COVID-19 vaccine program that took into consideration the provider type, capacity to serve as a mass vaccination provider, and priority populations served. This phased approach was discontinued, December 2020 opening enrollment to all licensed medical providers and institutions in Georgia. Active recruitment and enrollment of new providers will continue while the COVID-19 vaccines remain available.

COVID-19 Vaccine Program - Provider Enrollment

The GIP Program continues to lead the COVID-19 vaccine enrollment activities. COVID-19 vaccine providers may enroll by completing the Pandemic Vaccine Provider Profile and Provider Agreement on GRITS (https://www.grits.state.ga.us/). The "COVID-19 Program Provider Accountability and Waste Avoidance Policy" and "COVID-19 Vaccine Fraud Policy" should be reviewed for specific terms and



conditions of enrollment. The Provider's Chief Medical Officer (CMO) or their authorized designee must sign the "Acceptance of COVID-19 Vaccine Program Provider Accountability and Waste Avoidance Policy." The organization's chief medical officer (or equivalent) and chief executive officer (or chief fiduciary) must complete and sign the CDC COVID-19 Vaccination Program Provider Requirements and Legal Agreement. CDC's COVID-19 Vaccination Program Provider Profile Information must be completed for each vaccination location covered under the organization. The provider agreement and medical licenses or certification must be submitted for each health professional who will administer vaccine.

There must be a signed CDC COVID-19 Vaccine Redistribution Agreement for any facility/organization approved by DPH to conduct vaccine redistribution and a fully completed CDC COVID-19 Vaccination Provider Profile Information form (Section B of the CDC COVID-19 Vaccination Program Provider Agreement) for each receiving vaccination location.

The COVID provider enrollment assessment period lasts approximately five (5) to ten (10) business days for program requirement review and approval of your storage equipment (See Section 8 for specific vaccine storage and handling guidance).

For more information about how to enroll, please visit https://dph.georgia.gov/covid-vaccine-information-providers.

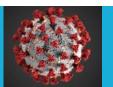
Pharmacy Enrollment

Participation by pharmacy partners remains a key component of vaccine distribution. Pharmacy partners not served directly by the CDC received information through DPH's Office of Pharmacy, the Pharmacy Disaster Response Coordinator pharmacist, the Georgia Board of Pharmacy, and respective state pharmacy associations regarding provider enrollment and vaccine guidance with support from the Office of Immunization.

Long Term Care Facility Enrollment

As part of a national vaccination strategy, all long-term care facilities had three options for assuring primary vaccination coverage for staff and residents.

- Facilities with the capacity to facilitate vaccination clinics for staff and residents, without
 external assistance, complete enrollment instructions as outlined above and register through
 GRITS to serve as a COVID-19 vaccination provider site.
- Enrollment in the Pharmacy Partnership for Long Term Care Program. Through this program, which is being phased out, CDC engaged two retail pharmacies, CVS and Walgreens, to secure the COVID-19 vaccine and provide onsite vaccination of residents at no cost to the facility.



 Leverage existing partnerships with local pharmacies, county public health clinics, etc., to provide vaccines for facility staff and residents. COVID-19 Vaccine Program Requirements for Providers

With the end of the Federal Pharmacy Partnership for Long Term Care Program, DPH assumed responsibility for assuring booster vaccine access for our LTCFs in Georgia. DPH released a survey to LTCFs in September 2021 to assess facility access to vaccines. Facilities who expressed a need for assistance are connected with a COVID vaccine provider who have agreed to assist DPH with booster vaccinations for our LTCF residents and staff. As an added resource, DPH partnered with Viral Solutions to cover any facility where access to a vaccine partner may be limited.

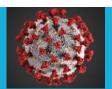
COVID-19 Provider Training

GIP has a list of training topics and a method for tracking provider training requirements through provider enrollment and quality assurance and improvement processes. Provider training requirements are located in the state GIP Manual in the Quality Assurance/Quality Improvement (QA/QI) section (Chapter 13). The learning expectations are based on the ACIP recommendations that outline the recommended Policies and Procedures for administering vaccines and providing immunization services by Registered Nurses (RNs) and Licensed Practical Nurses (LPNs) in a public health setting. The QA/QI tool is used to document the training/education expectations and clinical practice parameters for immunization services. The training tool is used to promote consistency in practice across programs on a statewide basis, provide an opportunity to identify excellence in practice, and provide opportunities for improvement. The training list and learning expectations will apply to all enrolled COVID-19 vaccine providers. Under Georgia's authority to administer vaccines during a state public health emergency, the training list and the QA/QI section of the GIP manual will be updated to include CDC guidance for COVID-19 vaccine(s) administration.

List of Training Topics

Before administering the COVID-19 vaccine, the learner will complete the following "You Call the Shots" CDC training modules: https://www2.cdc.gov/vaccines/ed/covid19/

- COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare
 Providers Understanding the Basics: The objective of this module is to provide healthcare
 providers with information about COVID-19 vaccine Emergency Use Authorization and safety,
 as well as general information about vaccine storage, handling, administration, and reporting.
 Training is available at https://www2.cdc.gov/vaccines/ed/covid19.
- Storage and Handling of COVID-19 Vaccines: The Vaccine Storage and Handling (1.0hr) training module is available on the CDC website https://www2.cdc.gov/vaccines/ed/covid19/SHVA/20010.asp. Training includes general



COVID-19 vaccine storage, handling, and transport information. The addendum will be updated as COVID-19 vaccine products are approved. Fact sheets for storage and handling are also available at https://www.cdc.gov/vaccines/covid-19/ to use as job aids for each COVID-19 vaccine. Additional information related to storage, handling, shipping, package, and transport are available below:

- a. **Pfizer-BioNTech COVID-19 Vaccine:** https://www.cvdvaccine-us.com/product-storage-and-dry-ice
- b. **Moderna COVID-19 Vaccine**: https://www.modernatx.com/covid19vaccine-eua/providers/storage-handling

COVID-19 Vaccine Administration: Vaccine Preparation and Administration training are available at the following links. Trainings include vaccine indications, vaccine preparation, vaccine administration, and documentation for COVID-19.

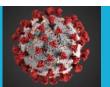
- a. Pfizer-BioNTech COVID-19 Vaccine Training Links:
 - i. https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html
 - ii. https://www.cvdvaccine-us.com/dosing-and-administration
 - iii. For additional information: https://www.pfizer.com/
- b. Moderna COVID-19 Vaccine Training Links:
 - iv. https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html
 - v. https://www.modernatx.com/covid19vaccine-eua/providers/dosing-administration
 - vi. For additional information: https://www.modernatx.com/

Emergency Use Authorization information with COVID-19 vaccine indications, contraindications/precautions, vaccine preparation, vaccine administration, and documentation are available at the following links:

- a. **Pfizer-BioNTech COVID-19 Vaccine:** https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html
- b. **Moderna COVID-19 Vaccine:** https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html
- c. **Janssen COVID-19 Vaccine:** https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html
- 3. Interim Guidance for Immunization Services During the COVID-19 Pandemic: The CDC developed a website for providers to access resources and FAQ document(s) to use as job aids and training material: https://www.cdc.gov/vaccines/pandemic-guidance/index.html

Interim CDC Clinical Considerations regarding COVID-19 vaccination includes, but is not limited to:

- Vaccinations of patients with underlying medical conditions
- Vaccination during pregnancy or breast-feeding



- Vaccination of children/adolescents
- Allergies

These resources can be accessed at https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

- 4. Documentation and Tracking of Provider Training: As part of the CDC COVID-19 Vaccination Program, each enrolled vaccination location will be required to submit training verification records for all providers covered under the organization as part of their Provider Agreement. Each COVID-19 provider will be required to sign the appropriate provider agreements and undergo training on how to utilize GRITS(IIS) functionalities, monitor and manage vaccine inventory within GRITS, and submit data. Training is available at https://www.gritstest.state.ga.us/docs/ManageOrders 20FEB 2014 Final Copy.htm.
- 5. Additional training and education materials for Healthcare Professionals and Jurisdiction can be accessed from the CDC website at https://www.cdc.gov/vaccines/covid-19/index.html.
- 6. ACIP COVID-19 Vaccine Interim Recommendations: https://www.cdc.gov/vaccines/covid-19/index.html

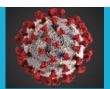
Section 6: COVID-19 Vaccine Administration Capacity

DPH's GIP and Emergency Preparedness and Response (EPR) began assessing vaccine administration capacity and vaccine provider interest in August 2020. Using Geographic Information Systems (GIS) vaccine administration data from GRITS, an evaluation of vaccine accessibility throughout the state was completed. These maps allowed Georgia to assess current capacity and identify pockets of need across the state.

Data elements include, but are not limited to:

- Provider type
- 2. Populations served as stated in the provider profiles
- 3. Vaccine storage capabilities
- 4. Number of vaccines on hand
- 5. Doses of vaccines administered

All maps were shared with our public health partners and others to be used for situational awareness purposes and assist with local vaccination efforts.



Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management

This section will be reviewed, revised, or updated as the situation develops, and additional guidance and recommendations are shared.

COVID-19 Vaccine Allocation and Distribution

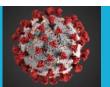
When the COVID-19 vaccine first became available for allocation, GIP utilized information collected from the COVID-19 Vaccine Pre-Enrollment Questionnaire (Appendix F). Data was extracted and filtered to prioritize providers with high volumes of Phase 1: frontline workers/first responders (hospitals, EMS, etc.), long term care facilities (LTCs), and the capacity to vaccinate their staff, patients, and community. In partnership with state public health's Office of Emergency Preparedness and Response, GIP utilized Geographic Information System (GIS) mapping to assess vaccine accessibility throughout the state. Provider type and populations served stated in the provider profiles were used to determining allocation prioritization. As more COVID-19 vaccine became available, GIP utilized this same method for allocating to providers of Phase 2: other essential workers and other vulnerable populations, and Phase 3: General Public (which would include children and other non-vulnerable adults).

June 2021, our federal partners lifted COVID vaccine allocations as vaccine supply surpassed vaccine demand. This allowed GIP to discontinue vaccine allocation processes. Providers are now allowed to submit weekly vaccine requests for order placement. Vaccine requests are reviewed by GIP staff and processed via one of the following methods:

- Vaccine requests are fulfilled through provider-to-provider transfers whenever possible. This strategy was implemented to reduce the potential of vaccine waste due to expiration.
- Vaccine requests are fulfilled from the DPH RSS through our vaccine re-distribution process. This
 strategy was implemented to assist providers who do not have the patient demand or storage
 capacity to accept, manage, or administer the minimum ordering amount available through the
 federal vaccine ordering system.
- Vaccine requests are submitted to CDC for direct shipment to provider locations with the capacity to receive, store, and administer larger vaccine shipments.

COVID-19 Vaccine Cold Chain Management

A key component in GIP's plan to incorporate COVID-19 vaccine allotments is by assuring providers can maintain cold chain capabilities. This is accomplished by collecting providers' documentation of completed vaccine storage and handling training required during the enrollment process and verifying proper working equipment for vaccine storage during physical and virtual site visits.



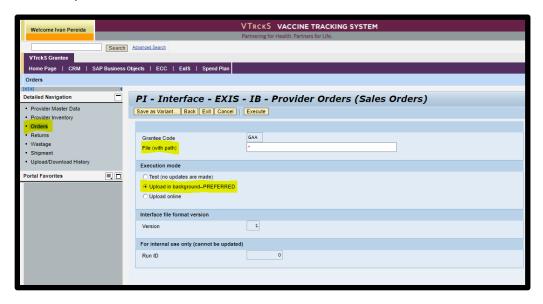
GIP adheres to vaccine manufacturer, ACIP, and CDC guidance regarding proper storage and handling of the COVID-19 vaccine and shared this information with COVID-19 providers. Updates to this guidance will be addressed in this plan and shared with providers upon receipt.

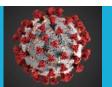
COVID-19 Vaccine Ordering

On June 2021, GIP moved vaccine ordering from utilizing SurveyMonkey to process providers' vaccine orders to the COVID-19 Vaccine Management System (VMS). VMS is an online system for inventory management, vaccine ordering, and dose administration reporting. VMS streamlines processes for the entire vaccine lifecycle.

In addition to VMS, DPH has implemented a vaccine ordering process specifically for Georgia Pediatricians utilizing ReadyOp. This process was created to service Georgia primary care providers and local health departments who requested smaller quantites of Pfizer BioNTech COVID-19 vaccine (60 doses packs and 120 dose packs) due to their limited cold chain management capabilities.

GIP completes a daily upload of provider information into the CDC Vaccine Tracking System (VTrckS) utilizing information collected from the COVID-19 Provider Profiles in GRITS. Mass uploads will continue as deemed necessary, and staff will individually upload/update a single provider's information in VTrckS on a case-by-case basis. Vaccine orders are processed via VTrckS EXIS Provider Orders (Sales Orders) Interface, similarly to how other seasonal Special Circumstance orders are processed, such as influenza a minimum of once per week.





Transfer or Redistribution of Vaccine

Providers should not transfer or redistribute COVID-19 vaccine without notifying GIP. Providers will have an IRC assigned to their site who will coordinate with GIP.

Vaccine Wastage and Inventory Levels

Tracking COVID-19 vaccine wastage/spoilage and inventory levels is recorded through VMS. Additional information on avoiding vaccine waste can be found in DPH's "COVID-19 Vaccine Program Provider Accountability and Waste Avoidance Policy."

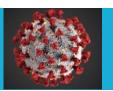
Section 8: COVID-19 Vaccine Storage and Handling

Cold chain storage and handling requirements for each vaccine product will vary from refrigerated (2° C to 8° C) to frozen (-25°C to -15°C) to ultra-cold (-90°C to -60°C) temperatures, and ongoing stability testing may impact these requirements. Vaccines must be stored appropriately from the time they are manufactured until they are administered to a patient. Excessive heat or cold may reduce vaccine potency, thereby increasing the risk that recipients will not be protected against vaccine-preventable diseases. Complying with state and federal laws and regulations relating to the storage, security, and distribution of vaccines is a requirement to assure quality pharmaceutical services consistent with attaining high pharmaceutical integrity standards for all recipients of COVID-19 Vaccine. Failure to maintain vaccine product integrity can result in patients inadvertently receiving a compromised vaccine, facilities unable to access or replace limited vaccine inventory, re-vaccination having to occur for patients, and loss of patient confidence.

The U.S. Pharmacopeia (USP) Chapter <659> "Packaging and Storage Requirements" provides examples of different temperature storage conditions. The following definitions have been provided and have been verified in the latest release of the USP <659> Chapter:

- FROZEN- Any temperature at -20°C (-5 degrees Fahrenheit). A freezer is a cold storage unit in which the temperature is maintained at -25°C and -10°C (-13°F and 14°F).
- Cold: Any temperature not exceeding 8°C. A refrigerator is a cold storage unit in which the temperature is maintained between 2°C and 8°C (36 to 46 °F).
- Cool: Any temperature between 8°C and 15°C (46°F and 59 °F)
- Controlled room temperature: The temperature maintained thermostatically that encompasses at the usual and customary working environment of 20°C-25°C(68°F-77 °F).
- Warm: Any temperature between 30°C and 40°C (86° and 104 °F).
- Excessive Heat: Any temperature above 40°C (104 °F).

U.S. Pharmacopeial Convention. USP General Chapter <659> Packaging and Storage Requirements. https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/659_rb_notice_english.pdf



Pfizer BioNTech COVID-19 Vaccine Storage and Handling

For the most up-to-date information, please visit the manufacturer's website at:

https://www.cvdvaccine-us.com/product-storage-and-dry-ice

Ultra-Cold Freezer

Before mixing, the vaccine may be stored in an ultra-cold freezer between -90°C and -60°C (-112°F and -76°F)

Freezer

Before mixing, the vaccine may be stored in the freezer between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks (14 days). This beyond-use date replaces the manufacturer's expiration date. The total time vials are stored at these temperatures should be tracked and should not exceed 2 weeks.

Refrigerator

Before mixing, The vaccine may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 1 month (31 days). After 31 days, vaccines must be removed from the storage unit and disposed of as biomedical waste.

Moderna COVID-19 Vaccine Storage and Handling

For the most up-to-date information, please visit the manufacturer's website at:

https://www.modernatx.com/covid19vaccine-eua/providers/storage-handling

Freezer

Unpunctured vials may be stored in the freezer between -50°C and -15°C (-58°F and 5°F). Vaccines must be stored in the original carton and protected from light. Do not store with dry ice or below -50°C (-58°F).

Refrigerator

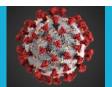
Unpunctured vials may be stored in the refrigerator between 2° to 8°C (36° to 46°F) for up to 30 days. After 30 days, vaccines must be removed from the storage unit and disposed of as biomedical waste. Do NOT refreeze thawed vaccine. Punctured vials may be stored between 2°C and 25°C (36°F and 77°F) for up to 12 hours.

Janssen (Johnson & Johnson) COVID-19 Vaccine Storage and Handling

For the most up-to-date information, please visit the manufacturer's website at:

https://www.janssencovid19vaccine.com/hcp.html

Refrigerator

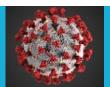


CDC recommends storing vaccine between 2°C and 8°C (36°F and 46°F), unpunctured until the expiration date. Punctured vials may be stored refrigerated for up to 6 hours. Providers should note the date and time the vial was first punctured. Vaccine not used within this time, should be removed from the storage unit and disposed of as biomedical waste.

Do Not Freeze Janssen Vaccine.

Individual Provider Locations Responsibilities

- COVID vaccine locations should ASSIGN responsibility for handling vaccines to a primary and secondary point of contact.
- 2. **CHECK** vaccine shipments immediately upon arrival.
- 3. STORE vaccines in a pharmaceutical-grade, commercial-grade, stand-alone unit, or ultra-cold storage unit. More information on proper COVID-19 vaccine storage can be found in the CDC's Storage and Handling Toolkit:
 - https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
 - The receiving facility will be responsible for tracking the vaccine product and maintaining cold-chain documentation for <u>any</u> verification purposes. The facility will agree to provide digital data logger files and temperature logs upon request from the Office of Immunization within 1 business day of the request.
- 4. **RECORD** temperatures at the beginning of the day using a digital data logger with a current certificate of calibration. Refrigerator temperatures should remain between 2°C-8°C (36°F to 46°F). Freezer temperatures should remain between -25°C to -15°C (-13°F to 5°F). Ultra-cold temperatures should remain between -90°C and -60°C (-112°F and -76°F). Temperature excursions outside of the required range should be reported to dph.ga.gov within 24 hours. All providers are required to have at least one backup digital data logger in the event the primary data logger malfunctions.
- 5. **ROTATE** vaccine stock to assure short-dated vaccines are administered before the expiration date
- 6. **REPORT** short-dated vaccines 30 days before expiration to your Immunization Regional Consultant (IRC) for potential redistribution, if needed.
- 7. RETURN
 - a. Thermal Shippers
 - i. Pfizer-BioNTech: https://contlogo.s3.eu-central-1.amazonaws.com/Pfizer/Thermal%20Shipper%20Return%20Guidance.pdf
 1. Video: https://www.cvdvaccine-us.com/product-storage-and-dry-ice
 - b. DPH is awaiting further Federal guidance regarding return processes and procedures.
- 8. **MAINTAIN** a completed Routine and Emergency Vaccine Handling Plan in an accessible location in the event of refrigerator/freezer malfunctions, natural disasters, etc. This plan should be reviewed monthly and updated as often as needed.



Satellite, Temporary, or Off-Site Settings

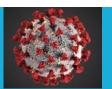
To increase equitable vaccine access to the COVID-19 vaccine, Providers may conduct satellite, temporary, or off-site clinics in collaboration with community stakeholders. Providers involved with off-site locations should assure that the vaccine cold-chain is maintained and follow COVID vaccine storage and handling practices.

Resources for off-site vaccination clinics that should be reviewed include but are not limited to the following:

- 1. CDC's Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Location https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html
- 2. CDC's COVID-19 Addendum to CDC's Vaccine Storage and Handling Toolkit https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
- 3. CDC's Guidance for Vaccination During a Pandemic https://www.cdc.gov/vaccines/pandemic-guidance/index.html

Additional considerations for off-site vaccination clinics

- The number of vaccines transported to an off-site or mass vaccination clinic should be based on the anticipated number of individuals to be served.
- Vaccines may be transported—not shipped—to a clinic site using vaccine transportation
 procedures outlined in CDC's Vaccine Storage and Handling Toolkit. Procedures include
 transporting vaccines to and from the site at appropriate temperatures and using appropriate
 equipment, as well as monitoring and documenting temperatures using a digital data logger
 with a probe in buffered material.
- Upon arrival at the clinic site, store vaccines correctly to maintain appropriate temperature throughout the clinic day. Maintaining temperatures includes reviewing temperatures every hour using a digital data logger with a digital display and a probe in a buffered material. At the end of the clinic day, the temperature data must be downloaded from the data logger and printed out. Make sure to document the date, location where the clinic was conducted, start time of transportation of vaccines, and end time of transportation of vaccines.
- If vaccines are exposed to out of range temperatures at any time, vaccines are to be labeled "do not use" until steps are taken to assure vaccines are viable. Providers must follow the steps located in the vaccine incident report
 (https://www.gritstest.state.ga.us/docs/Blank Vaccine Incident Report Rev 09132017.pdf) and follow up with the designated manufacturers. Even if vaccines are deemed viable, you are required to keep all documentation related to the incident
- Place a data logger in each portable storage unit containing an off-site vaccine.
- Monitor the temperature in each portable storage unit every hour from the time it is placed in the cooler(s) until it is returned to the refrigerator. There is an hourly temperature log for this



purpose. Download the data logger at the end of the off-site clinic and print a copy of the report.

Section 9: COVID-19 Vaccine Administration Documentation and Reporting

Providers have the choice to use the Georgia Registry of Immunization Transactions and Services (GRITS) through a direct interface between the provider's EMR and GRITS or DPH Vaccine Management System (VMS) to report COVID-19 vaccine doses administered. GIP will utilize data captured in both systems to report to CDC daily and report COVID-19 vaccination coverage on the DPH Dashboard.

GRITS is an Internet-based IIS operated by the GIP. GRITS was developed in 2003 to comply with Georgia Law (OCGA 32 12 3.1) as a birth to death registry. GRITS Enables providers to determine whether patients are due or overdue for an immunization; clarifies immunization schedules and emerging vaccine combinations; and manages vaccine inventory.

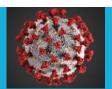
VMS is an online system for inventory management, vaccine ordering, and dose administration reporting. VMS streamlines processes for the entire COVID-19 vaccine lifecycle. VMS enables COVID vaccine management and data sharing for the State of Georgia on one central platform. Providers are able to request COVID vaccine and manage COVID vaccine inventory (e.g., vaccine dose administration reporting, complete documentation of provider to provider transfers, and vaccine wastage reporting) through VMS.

Reporting using IZ Gateway Connect

The COVID-19 Vaccination Reporting Specifications and Submission (CVRS) will be used to report COVID records to the CDC. Manual uploads of the CVRS will be made directly to the Data Clearinghouse daily.

Through the online Pandemic Enrollment feature in GRITS, each COVID-19 provider must complete and sign the designated provider agreement. Proof of online training (CDC's You Call the Shots - Storage and Handling Module, CDC's COVID-19 training module, and GRITS Manage Orders Online Training) is monitored through review of certificates documenting completed training, which are uploaded to GRITS. Pre-recorded trainings can be accessed and viewed at any time from the GRITS website, as well as personal trainings given to new GRITS users by Immunization Regional Consultants (IRCs) field staff in a train-the-trainer setting as deemed necessary. Written 'walkthrough' tutorials will also be available for distribution.

Providers will test all data exchange connections with an IIS analyst to assure smooth data submission. Once all training and testing have taken place, providers will be reminded that adherence to the binding agreements is pertinent. Consistent, timely reporting must be completed within 24 hours of administration.



In collaboration with Gainwell partners and Wisconsin Immunization Registry (WIR) Consortium members, GRITS is working to develop a mobile IIS app for out-of-office use. Users will be able to submit vaccine administration data records from off-site and temporary clinic settings by manual input. Records will either immediately be retained in the IIS or be uploaded upon returning to their office when outside the internet is not available.

In collaboration with Gainwell partners and Wisconsin Immunization Registry (WIR) Consortium members, GRITS is working to develop a mobile IIS app for out-of-office use. Users will be able to submit vaccine administration data records from off-site and temporary clinic settings by manual input. Records will either immediately be retained in the IIS or be uploaded upon returning to their office when outside the internet is not available.

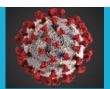
Data Entry and Reporting Monitoring

Districts received GIA funds, and some districts plan to use these funds to hire additional vaccine administrators. All vaccine administrators will follow data submission processes.

GRITS will instruct each user how to monitor data submissions with the "Check Status" function, which allows providers to review a log of all data records sent through data exchange, including percentages of error within each completed submission. District staff are able to review the monthly generated provider report card, which shows the target percentage of what GRITS expects to receive vs. the percentage of what is received, per data field.

Vaccine Inventory Reporting

Daily COVID vaccine inventory reporting is required by the Centers for Disease Control and Prevention (CDC). VaccineFinder, a public facing searchable data base, allows providers to list their on-hand vaccine inventory, vaccination locations, contact and appointment information. Pandemic providers upload their inventory and manage their publicly displayed information daily.



Section 10: COVID-19 Vaccination Appointment Reminders

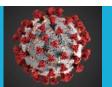
GIP program will utilize the IIS, GRITS, to enforce the use of the three following methods in conducting COVID-19 vaccine second dose, additional dose, and booster dose reminders:

- 1. Encourage COVID-19 vaccine providers to have vaccine recipients place a reminder on their cell phone: GIP will encourage COVID-19 vaccine providers to complete the vaccination record cards that will be included in every ancillary kit. Once accurate vaccination record card information is documented (i.e., vaccine manufacturer, lot number, dose administration, and future dose due date), the provider will be encouraged to ask recipients to take a photo of the vaccine record card. Providers should also encourage recipients to place a reminder for their next dose due date in their smartphone calendar (when applicable). Providers should tell recipients to bring vaccination cards with them when they return for future doses, as applicable.
- 2. Encourage COVID-19 vaccine providers to utilize their internal systems for future dose reminders: Many pharmacies and healthcare organizations have a system for their patient notifications and reminders, some using functionality within their electronic health record (EHR). Providers will be encouraged to use automated patient phone calls, emails, and text-message based systems for future dose reminders.
- 3. DPH will contract with a reminder recall vendor: DPH, through the Vaccine Registration and Administration Solutation (VRAS), will send future dose reminders to all COVID-19 vaccine receipients who schedule their vaccine appointments through VRAS. VRAS will also send reminders to vaccine recipients who received previous doses elsewhere but have registered and scheduled future doses through VRAS. GIP is aware of potential health plans assisting in notifying their enrollees about future doses based on filed COVID-19 vaccine claim information, and therefore providing additional redundancy for reminder methods.

Section 11: COVID-19 Requirements for IISs or Other External Systems

Description of Vaccine Related Data Elements

In addition to the required data elements listed in the CDC IIS Data Requirements for COVID-19 Vaccine Administration (Administered at a location, Administered at location: type, Administration address: city, Administration address: county, Administration address: state, Administration address: street, Administration address: zip code, Administration date, CVX (Product), Dose Number, IIS Recipient ID, IIS Vaccination Event ID, Lot Number: Unit of Sale, MVX, Recipient address: county, Recipient address: city, Recipient address: state, Recipient address: street, Recipient address: zip code, Recipient date of birth,



Recipient name, Recipient sex, Sending Organization, Vaccination Complete, Vaccine administering site, Vaccine expiration date, and Vaccine route of administration), GRITS is also able to collect race and ethnicity.

COVID Vaccine Dashboard - Link

Please select the link above (ctrl+click on "link") to access the COVID-19 Vaccine Dashboard.

Data Exchange and Reporting GRITS Capabilities

All GRITS users have the option of sending that data to the system electronically. GRITS accepts client/immunization files in either a batch flat file, batch HL7, or real-time HL7 (version 2.5.1) upload. Batch uploads are manual processes. Real-time interfacing is automated through WSDL web service or PHINMS connection. Most GRITS users utilize the interface functionality.

Server consolidation has taken place during second quarter of 2021, which moved GRITS to a cloud-based environment. This gives GRITS an unlimited amount of storage capacity.

GRITS & VMS Provider Access – Registration

GRITS

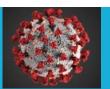
Enrollment in the GRITS database is a requirement for all vaccinating providers in Georgia. Providers who are not currently registered may begin this process by initiating an enrollment request via the GRITS online enrollment application (add link/web address). Onboarding registration can be handled within 24hrs or less. Registration includes gaining login credentials, scheduling training, and ascertaining needed functionalities (e.g., VFC enrollment, electronic data exchange, etc.).

VMS

Department of Public Health (DPH) sends email invitations to VMS users. Each invitation includes a direct link to the Georgia Provider Portal and an invitation code. The invitation code links a Microsoft account to a vaccine/coordinator record inside VMS. The invitation code creates a credential for VMS access. The invitation code will not pre-populate on the VMS log-in screen unless the direct link in the email is used to get to the Georgia Provider Portal.

Loss of System or Internet Connectivity

DPH continues to explore options to assure backup solutions are in place in the event system or internet connectivity issues occur. Discussions have included possible collaborations with other jurisdictions to develop a viable system-based solution, financially supported through a collective effort.



Data Quality Monitoring

GRITS' Provider Report Card highlights the completeness of an organization's electronic reporting fields. The report card provides a visual of the targeted percentage GRITS expects to receive vs. the percentage of what is received, per data field. Currently, the report is automatically generated for each health department monthly. COVID-19 providers not already included as part of another vaccine program will be added to that list.

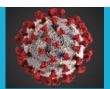
Section 12: COVID-19 Vaccination Program Communication

Communication plans have been established within the State DPH Crisis and Emergency Risk Communication (CERC) plan. The plan has been vetted, updated, and approved for use in emergencies with an all-hazards approach. Spokespersons for news conferences and media inquiries will be selected from within the GIP, and DPH leadership may include, but are not limited to, the GIP Director, GIP Subject Matter Experts, and DPH leads, including the Commissioner, the Health Protection Director, and the Communications Director. Every Communications endeavor outlined in this plan will be conducted with considerations to maximize health equity, providing information and vaccine services to those in the greatest need for the information and services.

The state DPH Division of Communications will lead the coordination of communication efforts about vaccine development and availability.

- The public will receive this information from the state DPH website, media reports, and additional marketing campaigns as funding allows. Information will be promoted through social media and updated as more information and resources become available from the CDC. The state DPH website includes an icon specifically for the use of public COVID-19 questions and concerns. A statewide COVID-19 hotline number is listed on the website and promoted elsewhere to address public questions and concerns. The public also can have questions and concerns addressed by phone, e-mail, or in-person, where possible, at all state and local DPH offices.
- Healthcare providers will be informed through regular communications, as established with the Regional Coordinating Hospital system, and directly through DPH Communications' constant contact list-serve.
- Partner agencies' informational updates on vaccine development and availability will be coordinated through the Joint Information Center (JIC) operations and redundantly through communications with the 18 Public Health districts and their communicators.

The DPH Division of Communications has and will continue to update media contacts with various media outlets, including tv, radio, newspaper, and on-line news services locally and statewide throughout Georgia.



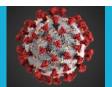
Vaccine public education will be coordinated through the GIP and DPH Division of Communications. Key audiences have been and will continue to be, identified by the GIP and the state DPH Division of Communications. Key audiences will receive targeted messages effectively and timely as set forth by the three anticipated phases of vaccine availability. Such key audiences will include but are not limited to employers, essential workers, those with limited access to vaccine services, and other major stakeholders in the healthcare system.

Plain language will be used in social media messages, infographics, news releases, and other methods of promoting Public Health messages throughout Georgia as part of a coordinated effort to assure a consistent approach to COVID-19 vaccination communication. Further educational outreach will be conducted through targeted marketing campaigns as funding allows. Outreach will be accomplished in phases, including 'Limited' vaccine supply, 'Increased Availability,' and 'Widely Available.' Communication plans for the phases of vaccine availability are outlined in the state DPH CERC plan's timed response actions.

Clear, concise, and consistent communication activities, taking into account social, economic, and demographical determinants, will be conducted to assure the highest possible public confidence in the efficacy of the COVID-19 vaccine. Communication will include information on what is known and what is still being researched transparently. Messaging to assure the highest public health and safety related to COVID-19 vaccination will follow the same pattern established through the first nine months of 2020. Messaging includes frequent updates to the website and posted information in the virtual JIC housed within WebEOC. Messaging may also include further development of infographics, fact sheets, and other communication tools available to all DPH and external partners.

The GIP and DPH Division of Communications will continue collaborative efforts to identify talking points and key considerations associated with COVID-19 vaccination endeavors. Efforts include identifying populations of focus who are at the greatest risk of negative outcomes related to contracting COVID-19. The DPH Division of Communications will coordinate with local Public Health districts to identify the atrisk populations and determine the most effective mediums to use in messaging to those key audiences. Coordination may include but is not limited to language consideration, spokesperson selection, and other facets of effective messaging. Plans are in place to expand such considerations externally through the DPH led Joint Information Center (JIC). The JIC was established on March 2, 2020. As of September 26, 2020, it includes 148 members from more than 50 local, state, and federal government and stakeholder agencies partnered for Communications in response to COVID-19 in Georgia.

The DPH Emergency Preparedness Limited English Proficiency/Sensory Impairment database identifies languages and communication means within each of the 18 health districts. Additionally, the database provides contact information on Phased levels for interpretation, translation, and other resource services. Additionally, local Public Health offices can provide resource capacity in the form of trusted community leaders and other partnerships to effectively reach all audiences.



Vaccine administration locations will be posted on the state DPH website in a timely, accurate fashion and on the 18 Public Health districts' digital properties within Georgia. Locations will be shared with the public, media, and partners to reach the largest audience, focusing on making the information available to those targeted audiences that are the most vulnerable, thereby in the greatest need of receiving a vaccination. Similar strategies were developed and improved statewide to promote COVID-19 Specimen Point of Collection (SPOC) locations. The uptake of the COVID-19 vaccine will be tracked and monitored by GIP and information shared internally. External information may be shared through Communications as deemed necessary by the Division of Communications, GIP, and DPH leadership.

Section 13: Regulatory Considerations for COVID-19 Vaccination

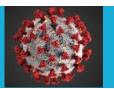
Currently, COVID-19 vaccines authorized under a EUA issued by the FDA are being administered to eligible recipients. August 23, 2021, the FDA approved the first COVID-19 vaccine, best known as the Pfizer-BioNTech COVID-19 Vaccine. This vaccine, once released for distribution in the US will be marketed as Comirnaty, for the prevention of COVID-19 disease in individuals 16 years of age and older. This vaccine will continue to be available under current EUA for all eligible populations. Additional COVID-19 vaccines may also be approved as licensed vaccines. DPH will continue to monitor this development and share the below plans with COVID-19 providers under both scenarios. To provide proper vaccine administration and patient care, DPH will observe ACIP COVID-19 vaccine recommendations.

Scenario 1: Emergency Use Authorization (EUA)

The EUA authority allows FDA to authorize either (a) the use of an unapproved medical product (which includes vaccine) or (b) the unapproved use of an approved medical product during an emergency based on certain criteria. If the COVID-19 vaccine is released under a EUA, the EUA will provide specific guidance regarding how the COVID-19 vaccine should be used and any conditions that must be met to use the vaccine. The "condition of authorization" will be discussed and confirmed between the FDA and CDC. Conditions are expected to cover distribution requirements, reporting requirements, and safety monitoring requirements. EUAs are authorized for a specific period and will expire at the end of the defined period. While the COVID-19 vaccine remains under an EUA, COVID-19 providers will be required to provide a copy of the EUA fact sheet to each patient, parent, or guardian before the vaccine is administered.

Scenario 2: Licensed Vaccine

VISs are required after a vaccine has been licensed and added to the Vaccine Injury Table. Planning for developing VIS for the COVID-19 vaccine is still being discussed at the federal level. Once made available, COVID-19 providers will be required to provide a copy of the VIS to each patient, parent, or guardian before the vaccine is administered. DPH will continue to monitor this situation and update this plan as additional guidance is received.



FDA authorized full licensure for Pfizer-BioNTech COVID-19 vaccine on August 23, 2021 for 16 years of age and over; the first mRNA COVID-19 fully licensed vaccine in the United States. DPH anticipates distribution of the licensed vaccine will begin December 2021. More information may be found here: https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.

Section 14: COVID-19 Vaccine Safety Monitoring

Providers authorized to administer vaccines are required by federal law to report to VAERS any adverse event following immunization, including a vaccine administration error. The CDC Vaccine Adverse Event Reporting System (VAERS) policy is located in the GIP Manual (Chapter 4) accessible on the DPH website https://dph.georgia.gov/immunization-section/immunization-publications. GIP will include VAERS reporting procedure job aids and website information in provider training materials and resources. CDC has developed a website and an Interim Guidance for Providing Vaccinations Safely During A Pandemic, which will also be shared with providers. GIP will share all CDC COVID-19 safety information on the DPH website.

V-Safe

V-Safe is a new voluntary, smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins for COVID-19 vaccine recipients. V-safe allows participants to report any side effects after the COVID-19 vaccination to CDC in almost real-time. It also gives them a convenient reminder to get their second COVID-19 vaccine dose if they need one.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

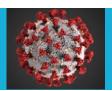
National Healthcare Safety Network (NHSN)

An acute-care and long-term care facility monitoring system that will promote reporting to VAERS. The new COVID-19 vaccine safety surveillance systems and any additional information sources will be shared with providers as it becomes available. https://www.cdc.gov/nhsn/index.html

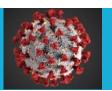
Section 15: COVID-19 Vaccination Program Monitoring

The GIP will assume responsibility for continuous monitoring for vaccine-related situational awareness throughout COVID-19 vaccination response activities GIP will review available CDC dashboards (e.g., Weekly Flu Vaccination Dashboard and COVID-19 Vaccination Response Dashboard), as additional monitoring tools. GIP will work with the Pandemic Vaccine Planning Team to share identified issues and update this plan to address these issues. GIP will use the COVID-19 vaccine e-mail to provide an opencommunication stream between COVID-19 vaccine providers and our office.

Through the Administrative Order, DPH has ordered COVID-19 Program Providers to comply with DPH's Policy "COVID-19 Vaccine Program Provider Accountability and Waste Avoidance Policy." To evidence



acceptance of the requirements of the Policy, each Provider must sign an "Acceptance of COVID-19 Vaccine Program Provider Accountability and Waste Avoidance Policy." DPH has also implemented a "COVID-19 Vaccine Program Provider Fraud Policy." Together these memorialize DPH's monitoring of the COVID-19 Vaccination Program and the penalties and corrective action that can be required for identified fraud, abuse and/or vaccine waste.



Appendix

Appendix A: Acronyms

Appendix B: Core COVID-19 Vaccine Planning Team and List of State and Local Partners

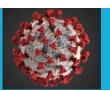
Appendix C: Georgia Priority Populations Vaccine Allocation Matrix

Appendix D: Critical Populations Data

Appendix E: Population Group Worksheet

Appendix F: COVID-19 Vaccine Pre-Enrollment Questionnaire

Appendix G: Georgia COVID-19 Vaccine Planning Frequently Asked Questions



Appendix A: Acronyms

ACIP: Advisory Committee on Immunization Practices

CDC: Center for Disease Control and Prevention

DPH: Georgia Department of Public Health

EUA: Emergency Use Authorization

FDA: Federal Drug Administration

GEMA: Georgia Emergency Management Agency

GIP: Georgia Immunization Program

GRITS: Georgia Registry for Immunization Transactions and Services

IIS: Immunization Information System (GRITS in Georgia)

MCM: Medical Countermeasures

MVC: Mass Vaccination Clinic

POD: Point of Distribution

SNS: Strategic National Stockpile

SOP: Standard Operating Procedures

VAERS: Vaccine Adverse Event Reporting System

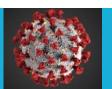
VIS: Vaccine Information Statements

VMS: Vaccine Management System

VTrckS: CDC Vaccine Tracking System

NHSN: National Healthcare Safety Network

WIR: Wisconsin Immunizations Registry



Appendix B: Core COVID-19 Vaccine Planning Team and List of State and Local Partners Georgia Vaccine Task Force

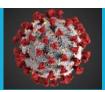
- Office of the Governor
- Office of Insurance and Safety Fire Commissioner
- Georgia Department of Public Health
- Georgia Emergency Management and Homeland Security Agency

Georgia DPH Core COVID-19 Vaccine Planning Team

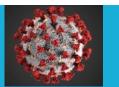
- Division Epidemiology
- Division of Health Protection
 - o Emergency Preparedness Program
 - o Office of Emergency Medical Services
- Division of Medical and Clinical Services
 - o Immunization Program
 - Office of Nursing
 - Office of Pharmacy
- Office of General Counsel

State and Local Partners

- Georgia Public Health Districts (18)
- Georgia Chapter of American Academy of Pediatrics
- Georgia Hospital Association
- Georgia Health Care Association
- · University System of Georgia
- Emory University
- Morehouse School of Medicine
- Georgia Primary Care Association
- Georgia Pharmacy Association
- Georgia Department of Community Health
- Georgia Department of Behavioral Health Disorders and Disabilities
- Georgia Alliant Quality Quality Improvement for Alliant Health Solutions



- Georgia Department of Agriculture
- Georgia Poultry Federation
- Georgia Chamber of Commerce



Appendix C: Georgia COVID-19 Vaccine Eligible Populations

Update: As of March 24, 2021, all residents of Georgia ages 16 and over are eligible to receive the COVID-19 vaccine. The Georgia Department of Public Health continues to expand vaccination populations for initial vaccine doses, boosters, and additional doses as CDC's ACIP updates recommendations and guidance based upon available data.

Update: As of November 2021, all residents of Georgia ages 5 and over are eligible to receive the COVID-19 vaccine. Specifically, ages 5 to 17 years are only eligible to receive Pfizer BioNTech mRNA COVID-19 vaccine; while 18 years and older are eligible to choose their preferred COVID-19 vaccine of choice.

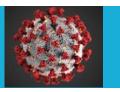
Adults with intellectual and developmental disabilities are defined by:

Intellectual Disability is a disability characterized by significant limitations in both intellectual functioning and in adaptive behavior, which covers many everyday social and practical skills. This disability originates before the age of 22.

A **developmental disability** is a physical or mental impairment that happens before the age of 22, is expected to last a lifetime, and impacts at least three activities of daily living. Activities of daily living include self-care; receptive and expressive language; learning; mobility; self-direction; capacity for independent living; and economic self-sufficiency.

Children with Complex Medical Conditions or who are at high risk for COVID complications include:

- Malignancies requiring active treatment
- Immunocompromised state (weakened immune system) including organ transplant (bone marrow or solid organ) within 2 years
- Critical congenital heart disease
- Asthma (moderate to severe)
- Sickle cell disease
- Diabetes
- Obesity (BMI >95%)
- Cystic fibrosis



- Significant neurologic injury or condition (e.g. hypoxic ischemic encephalopathy, traumatic brain injury, congenital anomaly, acute flaccid myelitis) with functional/developmental impairment (e.g. cerebral palsy, developmental disability, prematurity, mitochondrial disease)
- Technology dependence (e.g. BiPAP, trach)

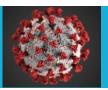
Moderately to Severely Immunocompromised people are especially vulnerable to COVID-19. This includes people who have:

- Been receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids or other drugs that may suppress your immune response

Immunocompromised individuals considering additional COVID-19 vaccine doses should consult with their healthcare provider about their medical condition.

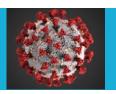
Booster Vaccine Recipients include certain populations based on age or risk for COVID-19 exposure and transmission.

 Please see the following link for the most up-to-date guidance and eligibility of COVID-19 vaccine booster doses: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html

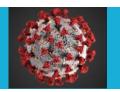


Appendix D: Estimating Critical Populations in Georgia

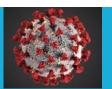
Healthcare Personnel			
Subpopulation	Identify	Estimate	Data Sources
Practicing Physicians	Georgia Board of Health Care Workforce (https://healthcareworkforce.georgia.gov/)	22,471	 https://healthcareworkforce.georgia.gov/document/publication/distribution-physicians-practice-settings-2015/download https://healthcareworkforce.georgia.gov/main-publications-reports/data-publications/counties-without-pcps https://healthcareworkforce.georgia.gov/physician-workforcedata
Practicing Physician Assistants	Georgia Board of Health Care Workforce (https://healthcareworkforce.georgia.gov/)	3,810	 https://healthcareworkforce.georgia.gov/physician-workforce-data https://healthcareworkforce.georgia.gov/physician-assistant-workforce-report
Practicing Nurses	Georgia Board of Health Care Workforce (https://healthcareworkforce.georgia.gov/)	141,117	https://healthcareworkforce.georgia.gov/physician-workforce- data
Psychiatrists	Georgia Board of Health Care Workforce (https://healthcareworkforce.georgia.gov/)	1,097	 https://healthcareworkforce.georgia.gov/document/publication/psychiatry-distribution-georgia-2015/download
Dentists	Georgia Board of Health Care Workforce (https://healthcareworkforce.georgia.gov/)	5,143	https://healthcareworkforce.georgia.gov/dentistry-workforce- reports
List of Providers (Physicians, Pharmacies, Nursing Services, Behavioral Healthetc.)	Georgia Department of Community Health (https://dch.georgia.gov/)	60,000 providers listed (some are facility- level)	https://dch.georgia.gov/providers/provider-directory
Directory of Pharmacists	Georgia Department of Community Health (https://dch.georgia.gov/)	TBD	https://gadch.mylicense.com/verification/Search.aspx
Critical Infrastructure Subpopulation	workers Identify	Estimate	Data Source



Law Enforcement	US Census Bureau Annual Survey of Public Employment & Payroll (https://www.census.gov)	2,706 (police) 15,689 (corrections)	https://www.census.gov/data/datasets/2019/econ/apes/annual- apes.html
First Responders			
Public Safety			
Education	U.S. Census Bureau Annual Survey of Public Employment & Payroll (https://www.census.gov)	105,442	 https://www.census.gov/data/datasets/2019/econ/apes/annual -apes.html
Food & Agriculture			
Energy Sector			
Water & Wastewater			
Transportation & logistics	US Census Bureau Annual Survey of Public Employment & Payroll (https://www.census.gov)	3,828 (Highways)	https://www.census.gov/data/datasets/2019/econ/apes/annual- apes.html
Public Works &			
Infrastructure			
Long-term Care Faciliti	es		
Subpopulation	Identify	Estimate	Data Source
	Georgia Department of Community Health (https://dch.georgia.gov/)		 https://dch.georgia.gov/announcement/2020-09-22/long-term- care-facility-covid-19-report
	Center for Medicaid and Medicare Services (https://data.cms.gov)	~27,000	 https://data.cms.gov/Special-Programs-Initiatives-COVID-19- Nursing-Home/COVID-19-Nursing-Home-Dataset/s2uc-8wxp
	Kaiser Family Foundation (https://www.kff.org/)	22,894	https://www.kff.org/other/state-indicator/number-of-nursing-facility- residents/?activeTab=map¤tTimeframe=0&selectedDistributions=number-of-nursing-facility-residents&sortModel=%7B%22colld%22:%22Location%22,%22sort%22:%22asc%22%7D



Subpopulation	Identify	Estimate	Data Source
People 65-years of	Georgia Online Analytical Statistical	1,516,954	 https://oasis.state.ga.us/oasis/webquery/qryPopulation.aspx
age and older	Information System		
	(https://oasis.state.ga.us)		
Homeless Population			
Refugees			
Migrant Workers			



Appendix G: Georgia COVID-19 Vaccine Frequently Asked Questions

1. What does mass vaccination mean?

Answer: A <u>mass vaccination pandemic site</u> is a site willing to serve their patients following normal business practices, as well as all members of the community during scheduled mass vaccination events.

2. How much will the vaccine cost?

Answer: There is no charge for the COVID-19 vaccine. The vaccines have been paid for with federal funds at no cost to the patient nor provider, which means that no one may be charged a fee for the vaccine itself.

3. If given to providers free of charge, can we charge patients an administration fee?

Answer: Providers may bill a patient's insurance for costs associated with the administration of COVID vaccine to administer each dose. However, providers are not allowed to bill the patient directly.

4. Are we agreeing to vaccinate the general population, not just our clinic's patients?

Answer: Providers can either be a <u>"mass" vaccination pandemic site</u> or a <u>"private" pandemic</u> vaccination site:

- a. If your clinic has the staff/capacity to serve your patients following normal business practices, as well as, members of your community during scheduled mass vaccination events, you will be designated as a <u>mass vaccination pandemic site</u> and eligible to receive vaccine supply to serve your patient population and members of your community.
- b. If your clinic *only* has the staff/capacity to serve your current patient population, you will be designated as a *private* pandemic vaccination site, and only receive vaccine supply to serve your patient population.
- 5. In what ways may hospitals, urgent care facilities, emergency medical services, and other facilities assist in the state's vaccination efforts?

Answer: You have three options. You can either be a closed vaccine point of dispensing (POD) site, "mass" vaccination pandemic site, or a "private" pandemic vaccination site:

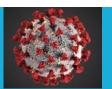
a. If your facility *only* serves your staff and your admitted patient population within current phase, you will be designated as a closed POD. These facilities will work with their local Public Health Emergency Preparedness team for more information on



- becoming a closed POD. Providers cannot vaccinate individuals that fall out side the current approved phases as a closed POD.
- b. If your facility has the staff/capacity to serve your in-patients and out-patients following normal business practices, as well as, members of your community during scheduled mass vaccination events, you will be designated as a <u>mass vaccination</u> <u>pandemic site</u> and eligible to receive vaccine supply to serve your patient population and members of your community.
- c. If your facility *only* has the staff/capacity to serve your current patient population, you will be designated as a *private* pandemic vaccination site, and only receive vaccine supply to serve your patient population.
- 6. If we are agreeing to vaccinate the population, what hours are required from us? Would this be after our normal business hours? During business hours? Are weekends required?
 - Answer: Your clinic will be responsible for setting your mass vaccination clinic hours and reporting these hours to the Georgia Immunization Program. Clinics should account for the needs of your patient population and the community when establishing hours.
- 7. What compensation will our employees receive for vaccinating the population?
 - Answer: While vaccine and ancillary supplies will be provided to participating providers at no cost to the provider or recipients, funding is not available to provide compensation for participating sites or your employees. Participation is voluntary.
- 8. Will supplies such as needles, syringes, Band-Aids, alcohol preps, and gauze be provided as they were when the H1N1 vaccine was released?

Answer: Yes, providers will receive two different types of kits based on the vaccine supply received:

- a. Administration Kits with needles, syringes, alcohol prep pads, facemasks, and face shields (all vaccines).
- b. Mixing Kits with needles/mixing syringes to support vaccines that require field mixing (as applicable).
- c. Sharps containers will not be supplied.
- 9. For pediatric clinical sites, does the vaccine logistics include administering to adults, as well?
 - Answer: Yes. If your clinic decides to be a <u>mass vaccination pandemic site</u>, you are agreeing to serve your patients and members of your community, including adults.
- 10. For adult clinical sites, does the vaccine logistics include administering to children, as well?



Answer: Yes. If your clinic decides to be a <u>mass vaccination pandemic site</u>, you are agreeing to serve your patients and members of your community, including children if the vaccine is approved by FDA for children.

11. Please explain how the program will roll out (logistics/planning type questions).

Answer: Vaccines will be released in a phased approach:

- a. <u>Phase 1:</u> Vaccines will be available in limited quantities and provided to enrolled providers to assure vaccination of our Phase 1 targeted populations.
- b. <u>Phase 2:</u> Vaccine will be available in higher quantities and provided to pandemic vaccination providers who agree to serve as mass pandemic vaccination sites and other providers who serve members of the Phase 2 targeted populations
- c. <u>Phase 3:</u> Vaccine will be widely available and provided to providers mentioned above, as well as providers who agreed to serve as a pandemic vaccine site. Vaccines will be available for general administration to the general public based on vaccine recommendations.
- 12. We only want to provide to our patients, if we do not participate, will we still have the vaccine to administer?

Answer: If you only want to provide the vaccine to your patients, your clinic will need to sign up as a "private" pandemic vaccination site. We will ship the vaccine to your site once available and based on the phases outlined above.

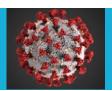
13. Will funding be provided to purchase vaccine storage units and other supplies for providers?

Answer: There is limited funding to support vaccine storage units and other supplies for district and county public health sites. However, private facilities will need to support their cold chain requirements.

14. Will there be a single-dose vaccine, or will a second dose be required at some point after the 1st dose?

Answer: Vaccine is available as both a two-dose series and single-dose vaccine. However, as new vaccines are developed and approved, vaccines may be available as both single-dose and two-dose series, to include different brands and preparations with varying administration schedules.

15. What procedures will be followed for the administration of the vaccine for children?



Answer: Children ages 5 years and older may receive only Pfizer-BioNTech mRNA COVID-19 vaccine.

16. Will the vaccine(s) go through the same FDA process as other vaccines, or have special considerations been made given due to the pandemic?

Answer: The FDA process has been streamlined for Project Warp Speed (The Federal COVID-19 vaccine development project). The vaccines will undergo a review and approval process with FDA, but the exact form of approval is still pending, e.g., standard approval, emergency use authorization (EUA), etc.

17. Will ancillary supplies be provided with the vaccine to local health departments?

Answer: Yes, ancillary supplies will be provided with the vaccines. Please refer to the response to Question 6 for more detailed information regarding anticipated supply kits.

18. Will contractual agency staffing be able to assist in giving the vaccine?

Answer: Yes, if it is within their scope of practice to administer vaccines and within the scope of the DPH contract.

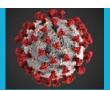
19. Who will give the injections at the closed POD locations?

Answer: Staff within the closed POD may administer a vaccine based on their clinical scope.

20. After reviewing the slide (trying to read between the lines), it appears that we may have two or more different manufacturers of vaccines, and if you start with one, the second dose must be the same brand. When shipping out the vaccine to the closed pods will someone make sure that they get the same brand each time they receive a shipment?

Answer: The allocations of vaccines will go through the DPH Office of Immunization and the CDC Distribution site. However, inventory management at the vaccination clinic site will play an important role in tracking this information and assuring the vaccine is available to complete the patient vaccine series. Staff should also use GRITS as a resource for confirming previous doses administered if the first dose was received at an alternate location.

21. What kind of paperwork will closed PODs complete, and how will the information get into GRITS?



Answer: Closed PODs should use electronic medical records and/or GRITS for data collection/submission. If a closed POD does not have access to GRITS, or their EMR does not interface with GRITS, please reach out to the Office of Immunization to work on a solution.

22. How will you make sure that closed PODs have digital data loggers and Koolatrons in place with a contact person to receive the vaccine?

Answer: Determining whether a location can support the cold chain requirements for the vaccine and having designated staff to oversee vaccine management practices within each location is part of the enrollment process for becoming a provider. These items must be confirmed before marking a site as an active provider.

23. Does the vaccine follow the same regulations for temperature monitoring as other vaccines the state provides?

Answer: Yes. Temperature monitoring requirements will be the same as other vaccines.

24. Are you developing just in time training with regards to the administration of the vaccine as well as storage and handling?

Answer: Yes. Just in Time Training has been developed and shared with all vaccine providers.

25. Will vaccines be shipped to jails/ correctional institutions once the critical workforce has been vaccinated?

Answer: No. Federal correctional institutions will receive guidance and vaccine directly from the CDC. If local public health would like to vaccinate at their county or local jails and are trying to develop a relationship, we have contacts with the 'Sheriff's Association to help establish the relationship, if needed. Additionally, the state vaccination planning team will work with the Georgia Department of Corrections to address their vaccination needs.

26. Should DPH Health Districts plan for the distribution of vaccines to EMS?

Answer: Vaccines will be shipped to EMS sites directly from CDC's distribution center if they are actively enrolled as pandemic vaccine providers with the Office of Immunizations. If a district would like to support the storage of the vaccine to help its EMS partners, they may do so but need to assure they have the capability/capacity to do so.

27. Do we need to plan for the cold chain for pre-filled syringes?



Answer: This is a possibility, so please prepare for all presentation types (multidose vials, single-dose vials, and pre-filled syringes).

28. Can a closed POD plan for vaccination of targeted partners? For example, EMS vaccinating other first responders in the county.

Answer: Yes, they should be able to administer the vaccine to other public safety agencies. Please make sure the EMS service provider consults their medical director for approval and coordinate with the DPH Office of EMS.

29. When will community engagement communication strategy documents be made available to begin education?

Answer: The CDC released guidance that includes communication strategies. The DPH COVID-19 Planning Committee is working to develop a state plan that will include these strategies and provide a guide to vaccination partners once finalized.

30. How much education will be given to the public before vaccine administration?

Answer: Development and release of educational information will continue throughout this response. As we receive information from the CDC regarding education and guidance, we will work with DPH Communications, our state public health partners, and the districts to develop and implement appropriate education strategies.

31. Does the State know the cold chain requirements for each of the products?

Answer: Please refer to the product insert as storage requirements will differ between vaccine brands:

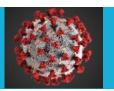
1. Refrigerated: 2-8C

Frozen: -20C
 Ultracold: -80C

32. If given "free," how will we know if someone goes to another source to get the vaccine and then chooses to come to our facility to receive an additional vaccine?

Answer: All vaccinations should be recorded in GRITS following administration. This will allow clinical staff to view the recipient's record to determine vaccine history if this is suspected of an individual.

33. Can providers get assistance with expanding cold chain capacity?



Answer: If it is a public health county/district-based provider, yes. Please contact the Office of Immunization for further guidance. If it is a private provider, they should procure their cold chain management.

34. How do we dispose of the expired vaccine?

Answer: Continue to provide a vaccine until it has reached its expiration date. If a vaccine expires, please document this appropriately and dispose of the expired vaccine following normal procedures for disposing biomedical waste. We will provide more information regarding expired vaccines following receipt.

35. Where can I find information regarding liability immunity for covered persons during an emergency response event?

The <u>Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for Medical Countermeasures Against COVID-19</u> provides liability immunity to covered persons. The <u>third amendment</u> to the declaration defines "covered persons".

36. When will COVID-19 vaccine arrive in Georgia?

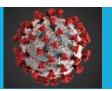
The first doses of COVID-19 vaccine arrived in Georgia in mid-December. Initial supply is limited and individuals receiving the vaccine will be prioritized based on risk of exposure and transmission.

37. Who should be vaccinated against COVID-19 infection?

The goal is for everyone to be able to easily get vaccinated against COVID-19 as soon as large enough quantities are available. Once vaccine is widely available, the plan is to have several thousand vaccination providers offering COVID-19 vaccines in doctors' offices, retail pharmacies, hospitals, federally qualified health centers and county health departments.

38. Who will get vaccinated first?

The Georgia Department of Public Health followed the recommendations of the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP) for prioritizing vaccination. Based on the risk of infection and transmission of COVID-19, and ethical concerns, ACIP has recommended that healthcare workers and residents of long-term care facilities be the highest priority groups to receive vaccine. Beginning on January 11, 2021, adults over the age of 65 and police and fire personnel were also made eligible to receive vaccine.



39. When the vaccine becomes available to the public where can I go to receive it?

The vaccine will be available throughout Georgia. Once widely available to the general public you will be able to receive it from any location/provider that is enrolled as a COVID-19 vaccine provider – this includes private healthcare providers, health departments, pharmacies and hospitals.

40. What is ACIP?

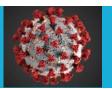
The CDC Advisory Committee on Immunization Practices (ACIP) is a panel of medical and public health experts and medical ethicists who develop recommendations on the use of vaccines in the United States. The recommendations provide public health guidance for safe use of vaccines and related biological products.

41. What is an EUA?

In certain public health emergencies, FDA may issue an Emergency Use Authorization or EUA which allows a drug or vaccine to be used when there are no alternate treatments or vaccines available. The FDA may grant an EUA once studies have demonstrated the safety and effectiveness of a vaccine but before the manufacturer has submitted a full license application and/or before the FDA has completed its formal review of the license application.

42. When can I get a COVID-19 vaccine booster if I am NOT in one of the recommended groups?

Additional populations may be recommended to receive a booster shot as more data become available. The <u>COVID-19 vaccines approved and authorized in the United States</u> continue to be <u>effective</u> at reducing risk of severe disease, hospitalization, and death. Experts are looking at all available data to understand how well the vaccines are working for different populations. This includes looking at how new variants, like Delta and Omnicron, affect vaccine effectiveness.



43. If we need a booster shot, does that mean that the vaccines aren't working?

No. <u>COVID-19 vaccines are working well</u> to prevent severe illness, hospitalization, and death, even against the widely circulating <u>Delta and Omnicron variants</u>. However, public health experts are starting to see reduced protection, especially among certain populations, against mild and moderate disease.

44. What are the risks to getting a booster shot?

So far, <u>reactions reported pdf icon</u>[4.7 MB, 88 pages] after getting the Pfizer-BioNTech booster shot were similar to that of the 2-shot primary series. Fatigue and pain at the injection site were the most commonly reported side effects, and overall, most side effects were mild to moderate. However, as with the 2-shot primary series, <u>serious side effects are rare</u>, but may occur.

45. Am I still considered "fully vaccinated" if I don't get a booster shot?

Yes. Everyone is still considered fully vaccinated two weeks after their second dose in a 2-shot series, such as the Pfizer-BioNTech or Moderna vaccines, or two weeks after a single-dose vaccine, such as the J&J/Janssen vaccine.

46. What is the difference between a booster shot and an additional dose?

A booster shot is administered when a person has completed their vaccine series and protection against the virus has decreased over time. Additional doses are administered to people with moderately to severely compromised immune systems. This additional dose of an mRNA-COVID-19 vaccine is intended to improve immunocompromised people's response to their initial vaccine series.